BioZ.com®

Operator's Manual

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TABLE OF CONTENTS

1 INTRODUCTION 1
1.1 Theoretical Concepts 1

2 WARNINGS AND PRECAUTIONS 3
2.1 General Warnings 3
2.2 Precautions 3
2.3 Indications 4
2.4 Contraindications 4

3 SYSTEM FEATURES 5
3.1 Standard Features 5
3.2 Optional Features 6

4 GETTING STARTED 7
4.1 General System Overview 7
4.2 User Interface (Symbol Key) 8
4.2.1 Softkeys 8
4.2.2 Hardkeys 8
4.2.3 LED Indicators 12
4.2.4 External Connections 14

5 QUICK-START INSTRUCTIONS 17

6 BIOZ.COM® TUTORIAL 19
6.1 Startup 19
6.2 Patient Data Entry 20
6.3 Patient Monitoring (Demo Mode) 25
6.4 Printing 34
6.5 Reviewing Patient Records 35
6.6 Exiting a Monitoring Session 35

7 "LIVE" PATIENT MONITORING 37
7.1 Patient Preparation 37
7.1.1 ICG Sensors 37
7.1.2 Skin Preparation 37
7.1.3 ICG Sensor Application 37
7.2 Patient Monitoring 40
7.2.1 Blood Pressure without Starting ICG Monitoring Session 40
7.2.2 ICG Monitoring Session 41
7.2.3 Softkeys 41
7.2.4 Patient Data Entry Fields 41
7.2.5 Patient Monitoring Screens 51

8. DETAILED DESCRIPTION 61
8.1. Welcome Screen 61
8.1.1 System Set-up 62
8.1.2 Configure Screens 78
8.1.3 Update Patient Information 84

8.2 Patient Records Management 85
8.2.1 Adding a New Patient 85
8.2.2 Add New Data to Previous Patient Record 85
8.2.3 Review or Delete Patient Records 85
8.3 Printing Information 89
8.3.1 Print Screen Report 89
8.3.2 Hemodynamic Summary Report 89
8.3.3 Hemodynamic Trend Report 90
8.3.4 Hemodynamic Status Report 90

9 TROUBLESHOOTING 93
9.1 Signal Acquisition Error 93
9.2 Low Battery 94
9.3 Printing Errors 94

10 NOMINAL SPECIFICATIONS 97

11 MAINTENANCE 99
11.1 Cleaning 99
11.2 Patient Cable 99

12 Z CARE® STANDARD WARRANTY 101

13 SOFTWARE LICENSE AGREEMENT 103

14 APPENDIX A. GLOSSARY OF TERMS 105

15 APPENDIX B. PRINT SCREEN REPORT 109

16 APPENDIX C. HEMODYNAMIC SUMMARY REPORT 111

17 APPENDIX D. HEMODYNAMIC TREND REPORT 113

18 APPENDIX E. HEMODYNAMIC STATUS REPORT 115

19 INDEX 117

TABLE OF FIGURES

Figure 1. Text Entry Screen 8
Figure 2. BioZ.com® Welcome Screen 19
Figure 3. Patient Data Entry Screen 20
Figure 4. Patient Data Entry Screen 21
Figure 5. Patient Data Entry Screen 21
Figure 6. Patient Data Entry Screen 22
Figure 7. Patient Data Entry Screen 22
Figure 8. Patient Data Entry Screen 23
Figure 9. Manual Blood Pressure Entry Screen 23
Figure 10. Patient Data Entry Screen 24
Figure 11. Patient Data Entry Screen 25
Figure 12. Monitoring Screen (Demo Mode) 26
Figure 13. BioZ.com® User Menu Screen 27
Figure 14. Password Entry Screen 27
Figure 15. Screen Configuration Menu 28
Figure 16. Monitoring Screen Configuration (1) 28
Figure 17. Monitoring Screen Configuration (2) 29
Figure 18. Hemodynamic Parameter Menu (1) 29
Figure 19. Monitoring Screen Cell Configuration Screen 30
Figure 20. Screen Configuration Menu Screen 30
Figure 21. User Menu Screen 31
Figure 22. Patient Monitoring Screen (Demo Mode, Re-Configured) 31
Figure 23. Diagnostic Screen (Demo Mode) 32
Figure 24. Therapeutic Screen (Demo Mode) 32
Figure 25. Trend Screen (Demo Mode) 33
Figure 26. Waveform Screen (Demo Mode) 33
Figure 27. Print Option Screen (Demo Mode, Re-Configured) 34
Figure 28. BioZ.com® Welcome Screen 35
Figure 29. Impedance Cardiography Sensor Placement Diagram 39
Figure 30. Independent Blood Pressure Screen 40
Figure 31. Blood Pressure Measurement Results Screen 40
Figure 32. Patient Data Entry Screen 41
Figure 33. Patient Data Entry Screen 42
Figure 34. Text Entry Screen 42
Figure 35. Patient Data Entry Screen 43
Figure 36. Patient Data Entry Screen 44
Figure 37. Patient Data Entry Screen 45
Figure 38. Patient Data Entry Screen 45
Figure 39. Patient Data Entry Screen 46
Figure 40. Manual Blood Pressure Entry Screen 48
Figure 41. Blood Pressure Out of Range Screen 48
Figure 42. Patient Data Entry Screen 49
Figure 43. Patient Data Entry Screen 49
Figure 44. Patient Data Entry Screen 50
Figure 45. Data Out of Range Screen 50
Figure 46. Monitoring Screen (Live Mode) 52

Figure 47. Manual Blood Pressure Entry Screen (Live Mode) 53
Figure 48. Data Out of Range Screen 54
Figure 49. Diagnostic Screen (Live Mode) 54
Figure 50. Therapeutic Screen (Live Mode) 56
Figure 51. Trend Screen (Live Mode) 57
Figure 52. Expandable Trend Screen (Live Mode) 58
Figure 53. Trend Screen Set-Up Screen (Live Mode) 58
Figure 54. Waveform Screen (Live Mode) 59
Figure 55. Welcome Screen 61
Figure 56. BioZ.com® User Menu Screen 62
Figure 57. BioZ.com® Set-Up Menu Screen 63
Figure 58. Alarm Status Screen 64
Figure 59. Alarm Limit Set-Point Screen 65
Figure 60. Alarm Reset Time Delay Screen 66
Figure 61. Password Entry Screen 67
Figure 62. Normal Range Gender Screen 68
Figure 63. Normal Range Menu Screen (1) 68
Figure 64. Normal Range Menu Screen (2) 69
Figure 65. System Default Menu Screen 70
Figure 66. BioZ.com® System Set-Up Menu (Screen 2) 72
Figure 67. Events List Screen 72
Figure 68. Password Entry Screen 73
Figure 69. New Password Entry Screen 74
Figure 70. New Password Re-Confirmation Entry Screen 74
Figure 71. New Password Verification Screen 75
Figure 72. System Set-Up Menu 75
Figure 73. Facility Name Entry Screen 76
Figure 74. Language Selection Screen 77
Figure 75. Custom Status Report Selection Screen (1) 78
Figure 76. Custom Status Report Selection Screen (2) 78
Figure 77. BioZ.com® Screen Configuration Menu Screen 79
Figure 78. Patient Monitoring Screen Cell Configuration Menu (1) 80
Figure 79. Patient Diagnostic Screen Cell Configuration Menu (1) 81
Figure 80. Hemodynamic Parameter Set-Up Menu (1) 81
Figure 81. Trend Screen Cell Configuration Menu Screen 82
Figure 82. Waveform Screen Cell Configuration Menu Screen 83
Figure 83. Patient Data Entry Confirmation Screen 84
Figure 84. Patient Data Entry Exit Screen 85
Figure 85. Patient Record Review Screen (1) 86
Figure 86. Patient Record Review Screen (2) 86
Figure 87. Patient Record Review Screen (3) 87
Figure 88. Patient Record Review Monitor Screen (4) 87
Figure 89. Poor ECG/Impedance Waveform Error Screen 93
Figure 90. Low battery Warning Screen 94

NOTE: Before using the BioZ.com®, carefully and completely read the instructions in this manual. If you do not understand the instructions or need additional information, contact CardioDynamics International Corporation (CDIC) at the address listed on page one of this manual.

1 INTRODUCTION

The BioZ.com® is an innovative noninvasive impedance cardiography (ICG) device that provides hemodynamic parameters based on the measurement of thoracic electrical bioimpedance. Specifically, the BioZ.com® allows for assessment of a patient's hemodynamic status and ventricular function by determining twelve (12) hemodynamic parameters as well as four (4) indexed parameters. In addition, the BioZ.com® allows the operator to:

- Observe trends in the patient's status
- Measure Blood Pressure Independently with Optional integrated Blood Pressure monitor
- View, store, and review the collected data and/or waveforms
- Print reports of the hemodynamic parameters with the date and time annotated accordingly
- Copy/Download files to a PC
- Utilize security precautions – Password protection for system configuration

1.1 Theoretical Concepts

Note: *The initial use of thoracic electrical bioimpedance was supported by impedance cardiography and plethysmography assessments. Today, many terms are used interchangeably when discussing impedance cardiography: Thoracic electrical bioimpedance (TEB), thoracic electrical impedance, and electrical bioimpedance. In this manual, the term impedance cardiography or ICG will be used.*

ICG is a technology that quantifies the mechanical activity of the heart (blood flow) as opposed to its electrical activity (ECG). The fundamental theoretical basis of ICG involves direct measurement of base impedance, velocity index, acceleration index, pre-ejection period, ventricular ejection time, and heart rate. These measurements are then used to calculate additional hemodynamic parameters.

The application of ICG to determine hemodynamic parameters is based on the following principles: Biological tissues, such as muscle, bone, fat and blood, all have different electrical properties. Of these tissues, blood is the most electrically conductive. Since arterial blood flow is pulsatile and arterial vessel walls are compliant, pulsatile changes in blood volume occur in the thoracic arterial system, predominantly in the aorta, as a result of ventricular function. This change in blood volume results in a change in the electrical conductivity and thus the impedance of the thorax to electrical current. Changes in the electrical impedance of the thorax are primarily due to changes in the velocity and volume of the blood in the aorta.

The BioZ.com® measures this change in impedance by injecting a high frequency (60 kHz Minimum), low amplitude (4.0 mA rms Maximum) alternating electrical current through the thorax between a pair of sensors placed on the neck and another pair placed on the mid-axillary line at the xiphoid process level. Use of a high frequency current eliminates the possibility of interference with bioelectrical

activity of the heart and brain. Additionally, as the skin-to-sensor impedance is very low at high frequency, there are no thermal effects to tissue, thus no sensation to the patient.

By detecting and measuring the change in thoracic impedance as a function of time, the BioZ.com® is able to *noninvasively* calculate stroke volume, cardiac output and many other hemodynamic parameters. In comparison, thermodilution *invasively* measures the change in temperature over a change in time in order to calculate stroke volume and cardiac output.

2 WARNINGS AND PRECAUTIONS

2.1 General Warnings

- **As a Class IIa, Type BF device under the Medical Device Directive, the BioZ.com® is not specifically intended to monitor variations in cardiac performance that could result in immediate danger to the patient.**
- **Caution: Federal law restricts this device to use by or on the order of a physician.**
- **Explosive Hazard: Do not use in the presence of flammable anesthetics or gases.**
- **Sensors are to be placed externally on the skin only and are not for direct cardiac application.**
- **The conductive gel of the sensors should not contact any other conductive materials during patient monitoring.**
- **For safe and proper operation this device is to be connected to a grounded receptacle. The Equipotential Bonding Receptacle (per DIN 42801) is provided for users who wish to connect the BioZ.com® device to the institution's equipotential system.**
- **To maintain compliance with Electromagnetic Compatibility (EMC) standards, if your device has an external Ferrite Core, it must remain attached to the patient cable (and keyboard cable when connected to the BioZ.com®) at all times.**
- **The patient cables specified and included with the BioZ.com® are designed specifically for protection against the effects of cardiac defibrillators and radio-surgery equipment. Do not use any other type of patient cable with this device.**
- **Disposal of this product and/or any of its accessories shall be in accordance with any and all local regulations.**
- **The printer and serial output and input ports on the back of the BioZ.com should only be connected to peripheral devices that meet the requirements of Safety Standard IEC 950. Consult the manufacturer or the user's manual of the peripheral device to verify that it complies with IEC 950.**
- **Caution! When monitoring patients with indwelling catheters, the printer must be used with a Hospital/Medical grade power supply. Should you have questions or require clarification, please contact CardioDynamics Technical Service for more information.**

2.2 Precautions

Impedance Cardiography (ICG) is a theoretical model of blood flow movement and is subject to inaccuracies in cases where the model does not fit a particular patient's clinical circumstances. Conditions that may limit the accuracy of the data are listed below:

- Septic shock
- Aortic valve regurgitation

- Severe hypertension (MAP > 130 mmHg)
- Patient heights measuring below 48" (120 cm) or above 90" (230 cm)
- Patient weights measuring less than 67 lbs. (30 kg) or greater than 341 lbs. (155 kg)
- Patient Movement
- Aortic Balloon Pump

Observe the following considerations when using the BioZ.com®:

- During open chest surgery, the BioZ.com® may produce inaccurate values because of the change in the normal pattern of blood flow and/or the electrical current flow through the chest cavity. In addition, during post-operative recovery monitoring, patient shivering and motion may produce excessive artifacts that may affect the accuracy of the BioZ.com®.
- Signal interference caused by other equipment may occur if cables and/or power cords of the BioZ.com® and other equipment cross over each other.
- The BioZ.com® should not be used concurrently on patients with Minute Ventilation pacemakers when the MV sensor function is activated.

2.3 Indications

- The BioZ.com® is designed for use with an adult in a resting position. The BioZ.com® and its components are not designed, sold, or intended for use except as described in this document.
- For hygienic purposes, single use patient sensors are specified when using this device.
- The BioZ.com® is a FDA Class II device.
- The blood pressure cuff provided with the BioZ.com® is non-conductive thus assuring no risk of burning the patient during radio surgical procedures such as electrocautery.
- The patient cable circuitry affords a high degree of patient isolation from potential ground faults.

2.4 Contraindications

None known.

3 SYSTEM FEATURES

3.1 Standard Features

The BioZ.com® interfaces with:

- Printers utilizing the Hewlett Packard PCL3 (and more recent) communication protocol
- External Keyboard
- IBM compatible PC's (with specialized software installed)

The BioZ.com® measures the following parameters:

- Thoracic Fluid Content (TFC): the inverse of the thoracic base impedance
- Indices of Contractility: reported as Acceleration Index (ACI) and Velocity Index (VI)
- Pre-Ejection Period (PEP)
- Left Ventricular Ejection Time (LVET)
- Heart Rate (HR)
- Blood Pressure (if optional module purchased)

The BioZ.com® calculates the following parameters:

- Cardiac Output (CO)
- Stroke Volume (SV)
- Systemic Vascular Resistance (SVR): also reported as Afterload
- Left Cardiac Work (LCW)
- Systolic Time Ratio (STR)

Several of the above parameters are indexed with reference to body surface area (BSA) to give indexed parameters. The BioZ.com® calculates the following indexed parameters:

- Cardiac Index (CI)
- Stroke Index (SI)
- Systemic Vascular Resistance Index (SVRI)
- Left Cardiac Work Index (LCWI)

3.2 Optional Features

The BioZ.com® is available with the following optional features:

- Internal Battery Power

  In the event that AC power becomes unavailable, the BioZ.com® will continue to operate for up to 30 minutes. An LED signal status light indicates the strength of the battery and a Charging LED indicates when the battery is being charged.

- Built-in Noninvasive Blood Pressure Monitor

  The BioZ.com® utilizes a noninvasive pressure cuff placed on the upper arm for obtaining the mean, systolic, and diastolic arterial blood pressure values. The noninvasive blood pressure monitor may also be used independently, without starting an ICG monitoring session.

- Serial Data Output

  The Patient Hemodynamic Parameter data may be accessed via the serial input port, and can be viewed in TAB delimited format.

4 GETTING STARTED

4.1 General System Overview

The BioZ.com® provides a user-friendly environment by which the User can easily enter patient information. Hemodynamic parameters are displayed by screens that are easily configured to User specified preferences. Display screens not only display the various parameters and/or waveforms, but also offer instructions to the User for accomplishing the many functions provided by the BioZ.com®.

A "Welcome" screen is the first screen displayed after system start-up (Figure 2). From the Welcome Screen the User may:

- Begin a patient monitoring session
- Take an Independent Blood Pressure measurement (optional feature, not available on all models).
- Run the Demonstration Program
- Access menus for various system configuration settings
- Review patient records

When monitoring a patient, the BioZ.com® provides five (5) basic screens for presenting the various hemodynamic parameters in a graphical, trending and/or data format. These screens are referred to as the Monitoring Screen, Diagnostic Screen, Therapeutic Screen, Trend Screen, and Waveform Screen. Each of these five screens is able to have its parameters and/or display configurations customized by the User.

To ensure accuracy and stability in the display of the parameters provided by the BioZ.com®, the data is averaged over a 30-heartbeat interval. The data is then updated (i.e., recalculated) and displayed every 10 heartbeats. Therefore, the displayed values are based on data from the 10 most recent beats plus the last 20 beats of the previous data update.

Note: The 30 beat Data Averaging frequency and 10 beat Display Update frequency are the default settings. The User may set the Data Averaging and Display Update Frequency from between one and 60 beats to meet their specific needs (see section 8.1.1.3).

Prior to monitoring a patient, it is recommended that the User become familiar with the BioZ.com® through the use of the tutorial presented in **SECTION 6, BIOZ.COM® TUTORIAL**, of this Manual. The Demo Mode is a comprehensive feature that provides the User with a pre-programmed patient case study. While in the Demo Mode, the User has access to all "Live Mode" features of the BioZ.com® including, but not limited to, screen configurations, selection of parameters to be displayed, and printing capabilities of data and/or reports. The Demo Mode provides the User with an excellent educational method for the operation and many features/configurations of the BioZ.com®. After completion of the Demo Mode Tutorial, the User should feel competent to begin a "live" monitoring session on a patient.

4.2 User Interface (Symbol Key)

The BioZ.com® consists of a 320 x 240 dot amber electroluminescent (EL) display screen with five software-defined operating keys located below the screen. These five keys will be referred to as **"softkeys"** throughout this document. In addition to the software-defined keys, there are hardware-defined keys, referred to as **"hardkeys"** throughout this document. Depending on the operational status of the BioZ.com®, not all the softkeys and hardkeys will be active at any given time. Any softkey or hardkey that is not active for a given screen, and pressed by the User, will evoke an audible signal but will not affect the operation of the BioZ.com® in any way.

4.2.1 Softkeys

Softkeys are screen specific (i.e., they perform different functions depending on the current screen display). For example, text entries may be performed with the softkeys. When it is necessary to enter text into a field (e.g., the Patient Name field, Facility Information), the following screen is displayed:

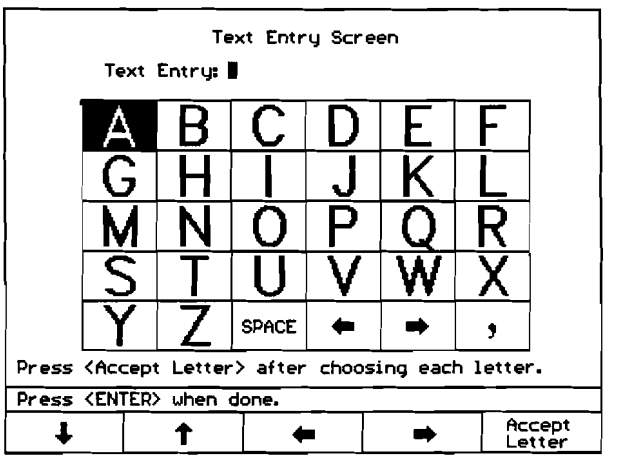


Figure 1. Text Entry Screen

The '↓, ↑, ←, →' softkeys are used to navigate through the alphabet in order to select the desired letter.

On the External Keyboard, keys <F1> through <F5> correspond to the five softkeys from left to right (i.e., the <F1> keyboard key is equivalent to the left most softkey on the BioZ.com®).

4.2.2 Hardkeys

4.2.2.1 Menu

The **'Menu'** hardkey is active from the Welcome Screen (Figure 2) and from the patient clinical monitoring screens. Pressing the **'Menu'** hardkey will take the User to a screen with five softkey choices acting as a menu. These softkeys will give the User access to menus that will provide control over system defaults/features and screen display configurations.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **M** keys.

4.2.2.2 Next Screen

The **'Next Screen'** hardkey is active only while a patient clinical data monitoring screen is displayed. Pressing the **'Next Screen'** hardkey cycles the User through the five screens in the following order: Monitoring Screen, Diagnostic Screen, Therapeutic Screen, Trend Screen, and Waveform Screen. The order then repeats. The **'Next Screen'** hardkey can also be used for scrolling through lists of patient records and lists of data records within a patient file.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **N** keys.

4.2.2.3 Previous Screen

The **'Previous Screen'** hardkey is active only when one of the five (5) patient monitoring screens are being displayed. Pressing the **'Previous Screen'** hardkey cycles the User through the five patient clinical data monitoring screens in the opposite order of the **'Next Screen'** hardkey. The **'Previous Screen'** hardkey can also be used for scrolling through lists of patient records and lists of data records within a patient file.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **P** keys.

4.2.2.4 Event

The **'Event'** hardkey is active while monitoring in both live and demo modes. Pressing the **'Event'** hardkey performs the function of attaching a User-defined text string to the patient record for use in patient summary and trend reports (see Section 8.3). There is a green LED indicator next to the **'Event'** hardkey that is energized while the BioZ.com® is storing the record.

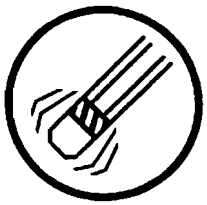
Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **E** keys.

4.2.2.5 Digits (0-9)

The 0-9 digit hardkeys are used in various menus where numerical input is required from the User.

Keyboard equivalent: 0-9 keys.

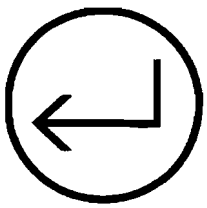
4.2.2.6 Clear



The **'Clear'** hardkey is used in various menus in conjunction with the 0-9 digit hardkeys. When a field is displayed that requires either an alphabetical or numerical entry from the digit soft/hardkeys, pressing the **'Clear'** hardkey will let the User erase an entry and start over.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **C** keys.

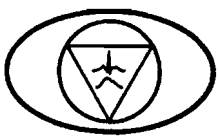
4.2.2.7 Enter



The **'Enter'** hardkey is used in various menus to accept a keyed-in or selected value.

Keyboard equivalent: Press the <Enter> key.

4.2.2.8 Stop Monitoring



Pressing the **'Stop Monitoring'** hardkey will stop the monitoring session and take the User to the BioZ.com® Welcome screen (Figure 2). The LED next to this hardkey is illuminated when no monitoring is taking place. The LED will be off while monitoring either an actual patient or when operating in demo mode.

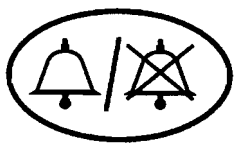
Keyboard equivalent: Press the <Esc> key.

4.2.2.9 Print

The **'Print'** hardkey is active at various times throughout the patient monitoring session, including all patient clinical data monitoring screens and the Review Records screens. After pressing the **'Print'** hardkey, a menu appears giving printing options (see section 8.3). After printing (a green LED is on when the BioZ.com® is communicating with a printer), the User returns to the screen of entry. A message is displayed informing the User of a connection problem if the printer does not respond.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **L** keys.

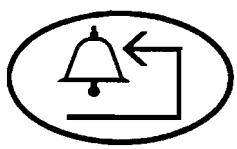
4.2.2.10 Alarm ON/OFF



Pressing the **'Alarm ON/OFF'** hardkey will enable and disable the BioZ.com® alarm system. An LED next to the hardkey will indicate green when the alarm system is enabled. The LED will automatically indicate red or amber (depending on the model) if the User disables the system, stops patient monitoring, or enters a message screen where the alarm system is not active. The alarm system will be enabled (and the LED indicate green) when monitoring is resumed.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **B** keys.

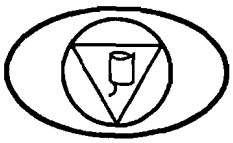
*4.2.2.11*Reset Alarm



The **'Reset Alarm'** hardkey is active only on patient monitoring screens when an alarm condition has been met. Pressing the **'Reset Alarm'** hardkey will silence the audible alarm for the amount of time established by the Time Delay default, if the alarm's audible feature is enabled (see section 8.1.1.1). The **'Reset Alarm'** function will not deactivate the visual alarm indicator; otherwise the User might forget which parameter triggered the alarm system.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **R** keys.

4.2.2.12 Manual Deflate (if equipped with BioZ.com® Blood Pressure module)



The **'Manual Deflate'** hardkey is used to manually trigger the BioZ.com® Cuff to deflate. This key gives the User control over the cuff in case of system malfunction or patient discomfort. During an error-free blood pressure measurement cycle, the cuff will deflate automatically.

Keyboard equivalent: Simultaneously pressing the **<Ctrl>** and **D** keys.

4.2.3 LED Indicators

In addition to the LED indicators associated with the hardkeys listed above, there are other LED Indicators associated with the operating status of the BioZ.com®.

4.2.3.1 Power Source Status

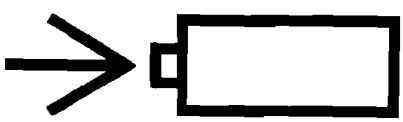
- **Mains AC**:

There is a green LED labeled **'Mains AC'** that is illuminated when the BioZ.com® is turned on and the power source is from either 110VAC or 220VAC.

- **Battery**:

If the BioZ.com® is equipped with the optional battery power source, there is a green LED, which may be labeled **'Battery'** that is illuminated while power is being supplied by the battery.

- **Charge**:



During charging of the battery (if equipped with the optional battery power source), an LED, which may be labeled **'Charge'** is illuminated.

4.2.3.2 Signal Strength Status

There are LED bar graphs that indicate the strength of the ECG and Impedance waveform signals and the Battery strength. When the signal is strong, the entire LED bar graph will be green. When the signal is weak, undetectable, or does not meet certain acceptance criteria, a single red or amber (depending on the model) LED will be energized at the left end of the bar.

- **ECG**

Automatic gain adjust is applied to the ECG signal for optimum detection and processing. The BioZ.com® records the number of gain changes that were applied in the previous 25 seconds. In general, the fewer gain changes, the higher the signal quality, and the more green LEDs displayed.

1 red LED (or amber depending on your model) = Four or more gain changes in the previous 25 seconds or no R wave detected within the last three seconds.

1 green LED = Three gain changes in the previous 25 seconds

2 green LEDs = Two gain changes in the previous 25 seconds

3 green LEDs = One gain change in the previous 25 seconds

4 green LEDs = Zero gain changes in the previous 25 seconds

- **Impedance**

The BioZ.com® applies specific rejection criteria to every heartbeat to determine the validity of the impedance signal. The Impedance signal status lights are dependent on the ratio of acceptable beats to total beats during the previous forty (40) beat interval.

1 red LED (or amber depending on your model) = less than 6 of the last 40 beats were acceptable

1 green LED = between 6 and 15 of the last 40 beats were acceptable

2 green LEDs = between 16 and 25 of the last 40 beats were acceptable

3 green LEDs = between 26 and 35 of the last 40 beats were acceptable

4 green LEDs = between 36 and 40 of the last 40 beats were acceptable

- **Battery**

1 red LED (or amber depending on your model) = less than 20 percent of full capacity

1 green LED = between 20 and 39 percent of full capacity

2 green LEDs = between 40 and 59 percent of full capacity

3 green LEDs = between 60 and 79 percent of full capacity

4 green LEDs = 80 percent or greater of full capacity

4.2.4 External Connections

4.2.4.1 Front Panel

- **NIBP Port** (If equipped with the optional BioZ.com® blood pressure monitor)
- **Patient Cable**

This symbol indicates that the device has type BF defibrillation protection.

4.2.4.2 Rear Panel

- **Warning Symbol**

With respect to electric shock, fire and mechanical hazards only, in accordance with UL 2601-1 <48 SK>.

- **Printer Port** – Uni-directional communication with Hewlett Packard PCL3 (and more recent) print language protocol printers.
- **Serial Output** – Not used at this time.

- **Serial Input** – Used when communicating with an external device, such as a PC.
- **Keyboard –** Allows a standard PC keyboard to be connected to facilitate data entry.

5 QUICK-START INSTRUCTIONS

NOTE: Before using the BioZ.com® for monitoring a patient, read all the information in this manual.

1. Cleanse the sensor sites and apply the sensors.
2. Connect Patient cable to the BioZ.com® and to the patient sensors.
3. If automatic blood pressure detection is desired, connect the blood pressure cuff to the BioZ.com® (if the model is equipped with this feature) and to the patient.
4. Connect the printer cable between the printer and the BioZ.com®. Connect the power cord to the printer and turn on the printer.
5. Turn the **'Power'** switch on the back panel to **On**. Ensure that the power cord is connected to either a 110VAC or 220VAC power source.
6. Press the **'Start Monitor'** softkey.
7. Enter the patient information; press **'Enter'**, or the '↓' directional arrow softkey after each entry.
8. Select the method of Blood Pressure determination (i.e., **'BioZ.com® Cuff'** or **'Manual Entry'**).
9. Press the **'Start Monitor'** softkey after all entries are complete.
10. The BioZ.com® displays the Monitoring screen. If necessary, press the **'Change ECG Vector'** softkey to obtain optimal ECG signal.
11. After 30 acceptable heartbeats (depending on the Data Averaging frequency), the BioZ.com® displays the first data set.
12. Press either the **'Next Screen'** or **'Previous Screen'** hardkeys to scroll through the various patient clinical data monitoring screens.
13. When finished monitoring, press the **'Stop Monitoring'** hardkey to end the session.

6 BIOZ.COM® TUTORIAL

The tutorial presented in this section should provide the User with a good working knowledge of the BioZ.com®. It is recommended that the tutorial be completed in the order presented. For a detailed description on an individual topic/feature, the User should refer to the respective section of this manual.

The Demo Mode allows a User to become familiar with the BioZ.com® without actually having a patient connected to the device. A pre-programmed waveform is stored in the device in order to represent an actual patient. All normal BioZ.com® features are accessible while operating in the demo mode. Any configuration changes made while operating in the demo mode will apply to all future actual-patient monitoring sessions. The tutorial will demonstrate how to change various default settings/configurations available on the BioZ.com®. By completing the tutorial, the User is afforded an ideal opportunity to configure the BioZ.com® to their specific requirements. The only differences between live mode and demo mode from a User's perspective are the following:

Each screen will have "Demo Mode" flashing in the lower right corner.

Note: If a patient is connected to the instrument while in "Demo Mode", the hemodynamic parameters and waveforms on the screen and recorded to the patient's file are not those of the actual patient.

6.1 Startup

1) Connect the Printer to the Printer Port located on the rear panel and turn the printer on.

2) Connect the keyboard to the 'Keyboard' connector located on the rear panel.

Note: It is necessary to perform the above steps prior to performing step 3.

3) Connect the power cord to the rear panel of the BioZ.com® and plug into either a 110VAC or 220VAC power source. Turn the Power Switch to the On position. The following screen will be displayed after the boot-up sequence is complete.

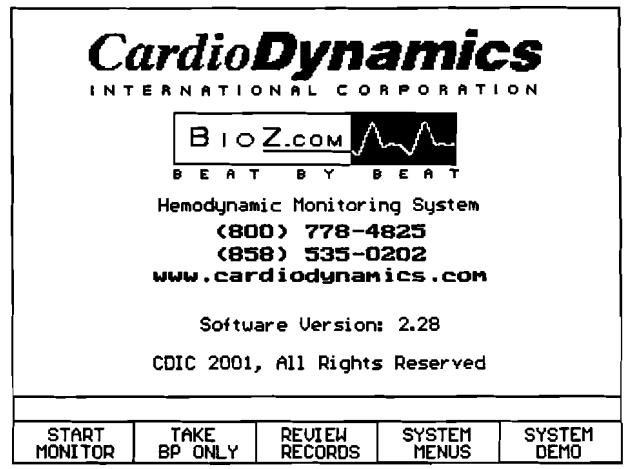


Figure 2. BioZ.com® Welcome Screen

4) Press the **'System Demo'** softkey. The following screen is displayed:

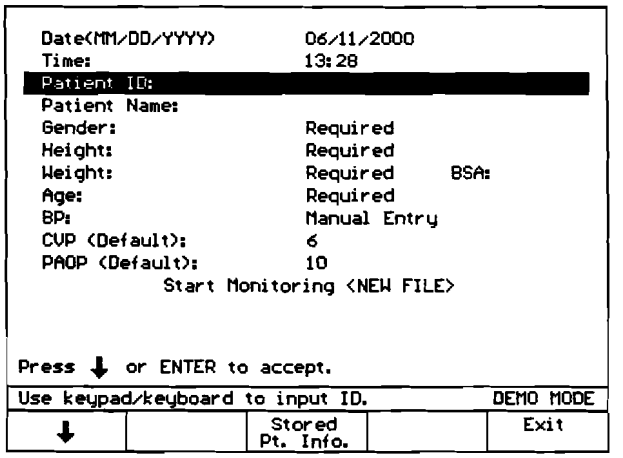


Figure 3. Patient Data Entry Screen

Note: When monitoring a patient for the first time, the User would press **'Start Monitor'**, not **'System Demo'**, and the above screen would be displayed. The only difference is that **'Demo Mode'** would not be flashing in the lower right corner.

6.2 Patient Data Entry

The Patient Data Entry screen allows the User to enter all the patient information required by the BioZ.com® to detect, process, and display various parameters relating to the patient's cardiac function. Except for the Patient ID and Name, all the fields displayed on the screen require User specific entries in order to begin a monitoring session.

1) In the Patient ID field, enter the patient's ID number by pressing the appropriate numerical hardkey(s)or typing from the keyboard. Up to nine (9) digits may be entered. Alphabetical characters can not be entered in this field. If an incorrect number is entered, press the **'Clear'** hardkey or the <Backspace> key if using a keyboard to re-enter the number.

2) Press the **'Enter'** hardkey or the '↓' softkey to advance to the Gender entry field. The following screen will be displayed:

Note: When in the demo mode, the Patient Name field will have **'Demo Patient'** locked in, and therefore it will be skipped over after an ID number has been entered. However, when conducting a live monitoring session on an actual patient, the highlight bar will advance to the Patient Name field.

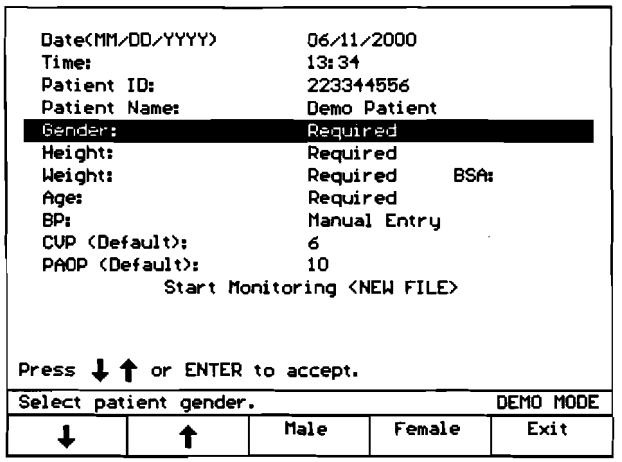


Figure 4. Patient Data Entry Screen

3) Press the **'Male'** or the **'Female'** softkey. The cursor will automatically advance to the Height field. The following screen will be displayed:

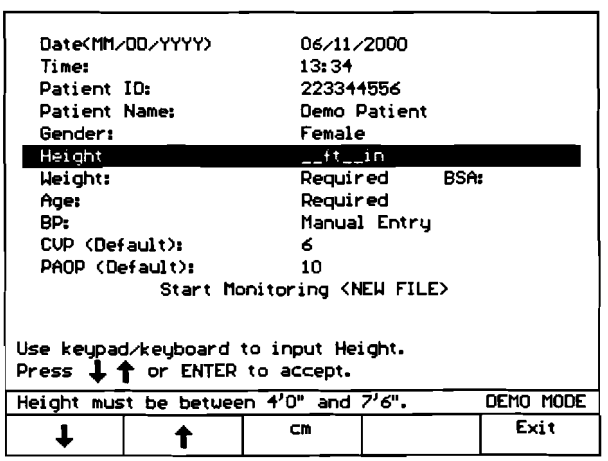


Figure 5. Patient Data Entry Screen

The accuracy of some of the data provided by the BioZ.com® may be compromised on persons under 120cm (4' 0") or over 230cm (7' 6") in height (see section 2.2, **Precautions**).

4) Press the appropriate numerical hardkeys in order to enter the 'ft' and 'in' data in the respective field, or press the **'cm'** softkey and enter the height in centimeters. Press the **'Enter'** or the '↓' key.

Note: If an entry greater than eleven (11) is entered into the 'in' field, the BioZ.com® will convert the entered value to it's equivalent feet and inch value. For example, **0 ft 71 in** may be entered in lieu of **5 ft 11 in**. If the value entered is out of the required range (i.e., less than **4 ft 0 in** or greater than **7 ft 6 in**) the User will be prompted to either accept or proceed prior to beginning the session.

Note: If **'Proceed'** is selected, the monitoring session can still proceed but data accuracy may be compromised.

If the value for the patient's height is within range, the cursor will automatically advance to the Weight field. The following screen will be displayed:

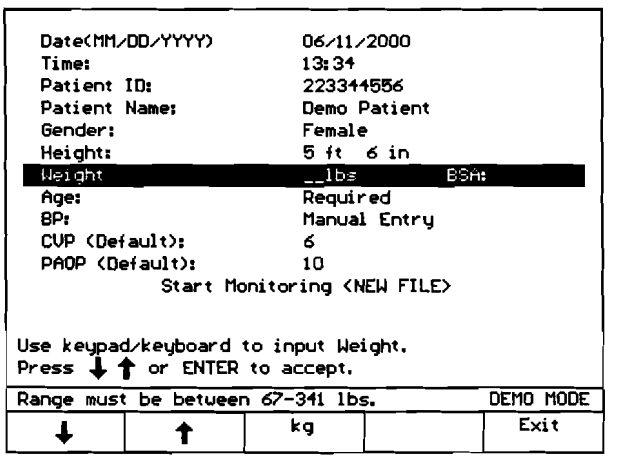


Figure 6. Patient Data Entry Screen

5) Press the appropriate numerical keys in order to enter the patient's correct weight (in units of lbs.), or press the **'kg'** softkey and enter the correct weight in units of kg. Press the **'Enter'** or the **'↓'** key, the cursor will automatically advance to the Age field. The following screen will be displayed:

   Note: The Body Surface Area (BSA) will be calculated and displayed after the weight has been entered.

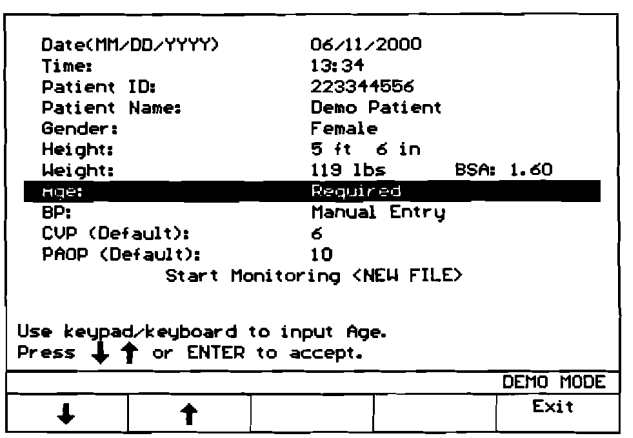


Figure 7. Patient Data Entry Screen

6) Press the appropriate numerical keys in order to enter the patient's age in years. Press the **'Enter'** or the '↓' key, the cursor will automatically advance to the Blood Pressure field. The following screen will be displayed:

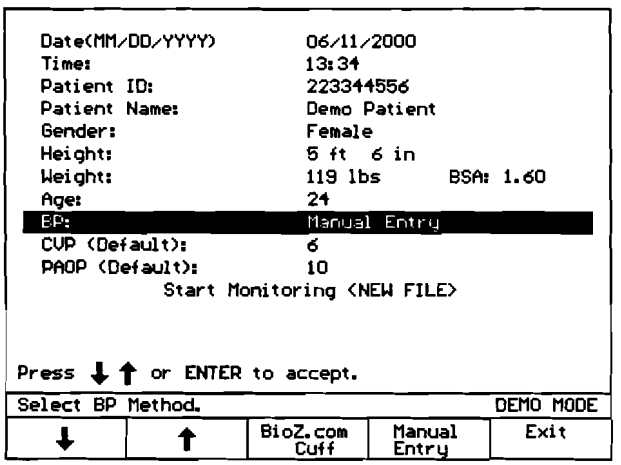


Figure 8. Patient Data Entry Screen

The BioZ.com® allows the User to select one of two methods for obtaining the patient's blood pressure: the BioZ.com® Cuff, or Manual Entry.

7) Press the **'Manual Entry'** key. The following screen will be displayed:

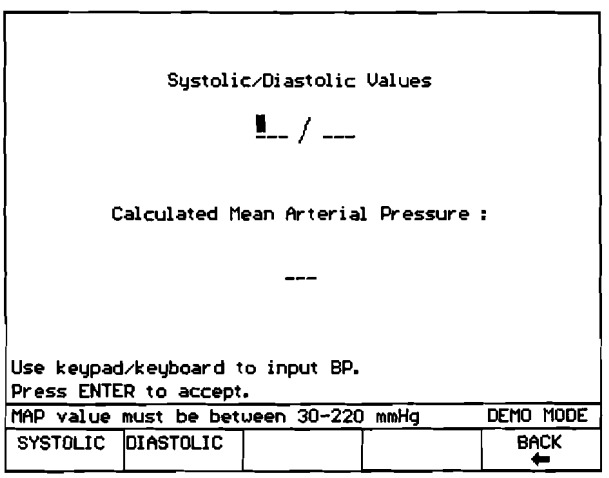


Figure 9. Manual Blood Pressure Entry Screen

8) Press the appropriate numerical keys in order to enter the correct systolic and diastolic pressures. Press **'Enter'**. If the calculated MAP is NOT within the allowed range, the "Data Out of Range" message screen (Figure 41) will be displayed; otherwise, the cursor will automatically advance to the CVP field. The following screen will be displayed:

Note: For information on obtaining blood pressure via the BioZ.com® Cuff, refer to section 7.2.4.7.

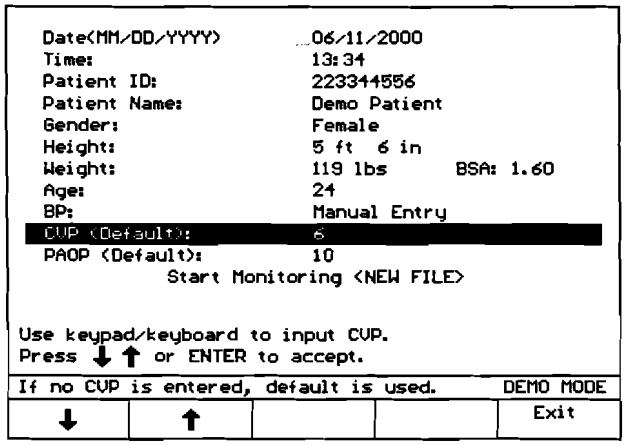


Figure 10. Patient Data Entry Screen

The BioZ.com® allows the User to enter the patient's actual CVP and/or PAOP. Refer to section 8.1.1.3 for a detailed description. If these values are not known, the BioZ.com® default setting for CVP and PAOP is 6 and 10 mmHg, respectively.

Note: CVP is used in the calculation of Systemic Vascular Resistance (SVR) and the Systemic Vascular Resistance Index (SVRI). PAOP is used in the calculation of Left Cardiac Work (LCW) and Left Cardiac Work Index (LCWI). Depending on the value for the Mean Arterial Pressure (MAP), for every one mmHg error in the CVP and/or PAOP a one to one and half percent error in SVR and/or LCW will be introduced.

For CVP / SVR:

$$SVR\ [\text{dyne sec cm}^{-5}] = (MAP - CVP) \times 80 / CO$$

If MAP = 90 mmHg, CVP = 6 mmHg, and CO = 5.5 L/min, then

$$SVR = (90 - 6) \times 80 / 5.5 = 1221\ \text{dyne sec cm}^{-5}$$

If the actual CVP was 8 mmHg (a 2-mmHg underestimation on the part of the BioZ.com®), then

$$SVR = (90\text{-}8) \times 80 / 5.5 = 1193\ \text{dyne sec cm}^{-5}$$

The percent error in the calculated SVR is:

$$\text{Percent error} = 100\% \times (SVR_{calc} - SVR_{true}) / SVR_{true} = 100\% \times (1221 - 1193) / 1193 = 2.34\%$$

Therefore, in this example, a 2-mmHg underestimation of CVP would result in a 2.34% overestimation of SVR.

For PAOP / LCW:

$$LCW\ [kg\ m] = 0.0144 \times (MAP - PAOP) \times CO$$

If MAP = 90 mmHg, PAOP = 10 mmHg, and CO = 5.5 L/min, then

$$LCW = 0.0144 \times (90 - 10) \times 5.5 = 6.3\ kg\ m$$

If the actual PAOP is 15 mmHg (a 5mmHg underestimation on the part of the BioZ.com®), then

$$LCW = 0.0144 \times (90-15) \times 5.5 = 5.94\ kg\ m$$

The percent error in the calculated LCW is:

$$Percent\ Error = 100\% \times (6.3-5.94) / 5.94 = 6.7\%$$

Therefore, in this example, a 5 mmHg underestimation of PAOP will result in a 6.7% overestimation of the LCW.

Press the '**Enter**' or the '↓' key twice in order to accept the default values. The cursor will automatically advance to the Start Monitoring field. The following screen will be displayed:

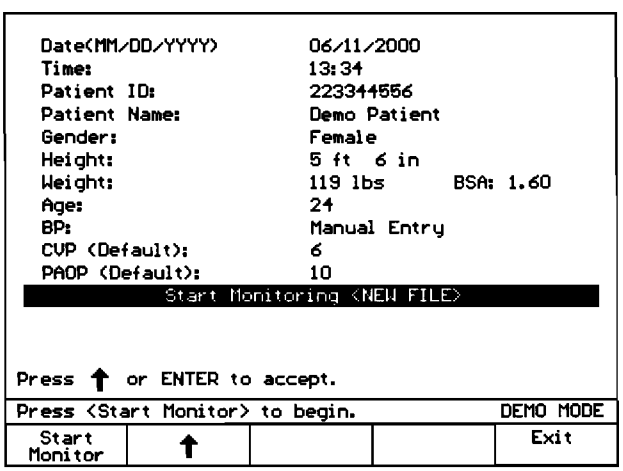


Figure 11. Patient Data Entry Screen

Press the **'Start Monitor'** softkey to begin monitoring.

6.3 Patient Monitoring (Demo Mode)

When monitoring a patient, the BioZ.com® provides five (5) basic screens for presenting the various hemodynamic parameters;

- Monitoring Screen
- Diagnostic Screen
- Therapeutic Screen

- Trend Screen
- Waveform Screen

Each of these five screens is able to have its parameters and/or display configurations customized by the User. The tutorial will demonstrate how to accomplish these changes.

1) Press the **'Start Monitor'** softkey to begin the monitoring session. The following screen will be displayed:

Note: If either the height, weight, or age were out of the recommended range, or omitted, an error message will be displayed prompting the User to enter or re-enter the correct values or Proceed with the monitoring session with the out of range values. If the User chooses to proceed, the calculated SV, SI, CO, CI, SVR, SVRI, LCW, and LCWI may not be an accurate indication of the patient's actual values.

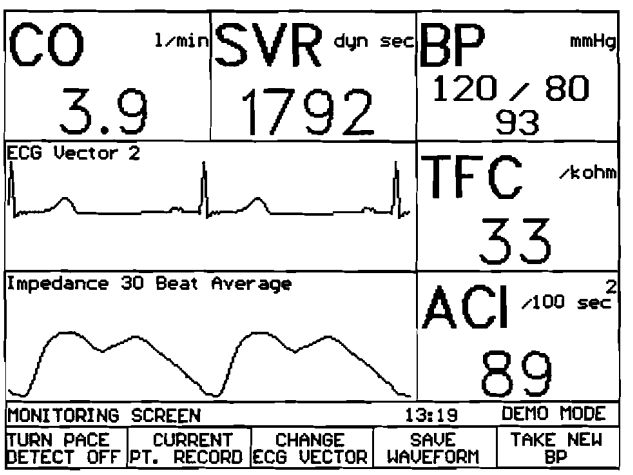


Figure 12. Monitoring Screen (Demo Mode)

Note: Your screen configuration may vary depending on previous configuration settings. The actual values will not appear until the appropriate number of heartbeats have been processed and accepted.

The Monitoring Screen consists of a maximum of five (5) data display cells and two (2) graphic display cells. The BioZ.com® provides the User with the ability to set the number of active graphic and data cells as well as the parameters displayed by those cells.

The **'Menu'** hardkey provides the User with access to the necessary screens for making custom changes to the BioZ.com®. To configure the Monitoring Screen:

2) Press the **'Menu'** hardkey. The following screen will be displayed:

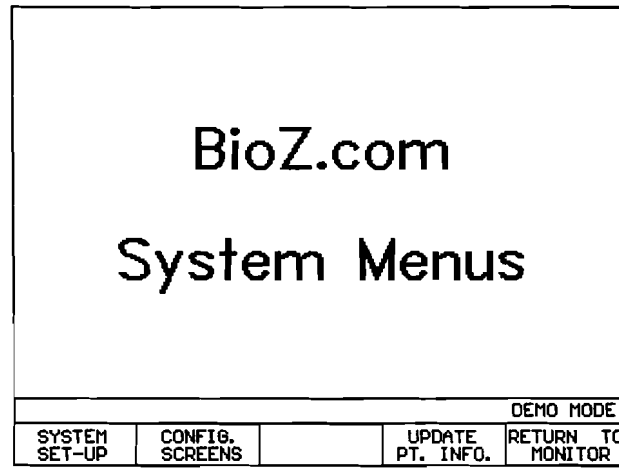


Figure 13. BioZ.com® User Menu Screen

The screen configuration menu on the BioZ.com® is password protected. A four (4) digit numerical password is required in order to make changes to the system default settings and/or screen configurations. The factory set default password is **1111**. If desired, the User may set their personal password at this time (see section 8.1.1.5).

3) Press the **'Configure Screens'** softkey. The following screen will be displayed:

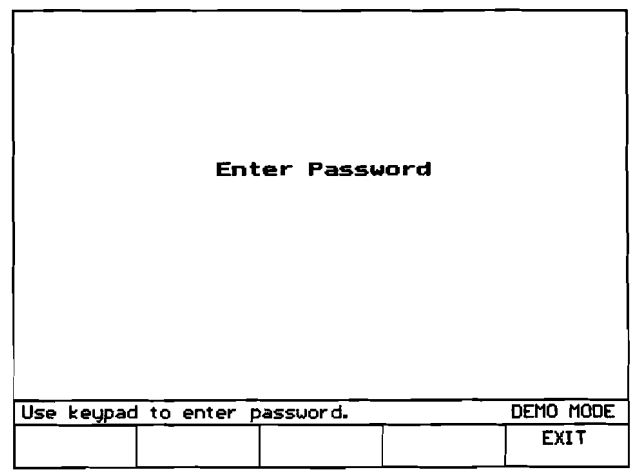


Figure 14. Password Entry Screen

4) Key in the correct password (**1111**, if the default password hasn't been altered). If the password was entered correctly, the following screen will be displayed; otherwise, you will be prompted to re-enter the correct password.

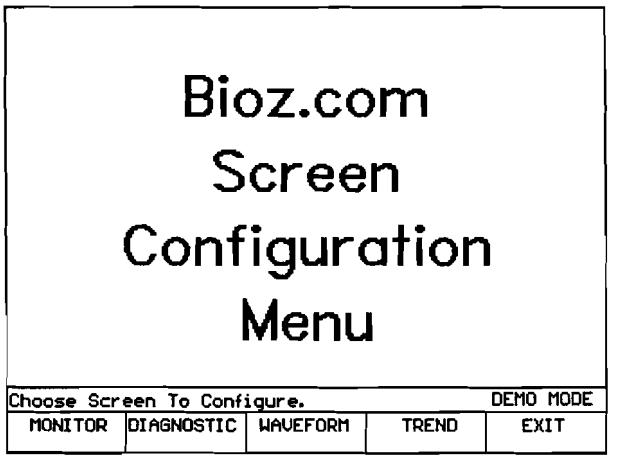


Figure 15. Screen Configuration Menu

The BioZ.com® allows the User to customize the screen configuration(s) to their requirements. For this tutorial, only the Monitoring Screen will be customized. The User should refer to section 8.1.2 to customize the configuration of the other patient monitoring screens.

5) Press the **'Monitor'** softkey. The following screen will be displayed:

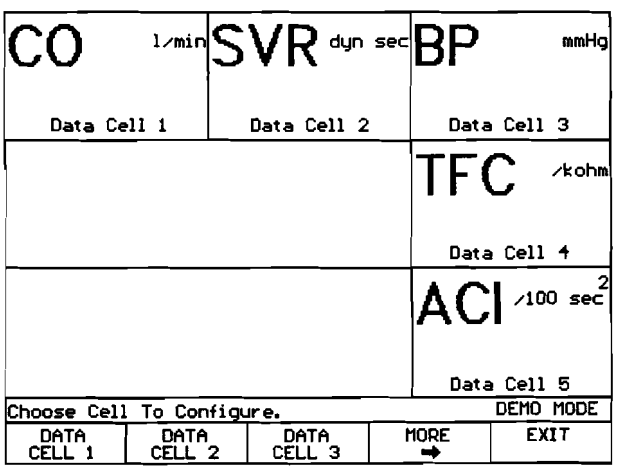


Figure 16. Monitoring Screen Configuration (1)

The User has the ability to choose the hemodynamic parameters that are displayed and the data/graphic cell in which they will be displayed. In this tutorial, Data Cells 4 and 5 will be deactivated. When both of these cells are deactivated, both Graphic Cells will "elongate" and fill the vacated screen area.

6) Press the **'More→'** softkey. The following screen will be displayed:

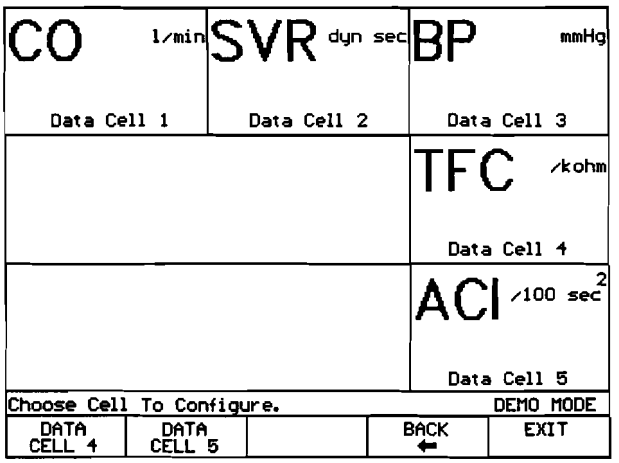


Figure 17. Monitoring Screen Configuration (2)

7) Press the **'Data Cell 4'** softkey. The following screen will be displayed:

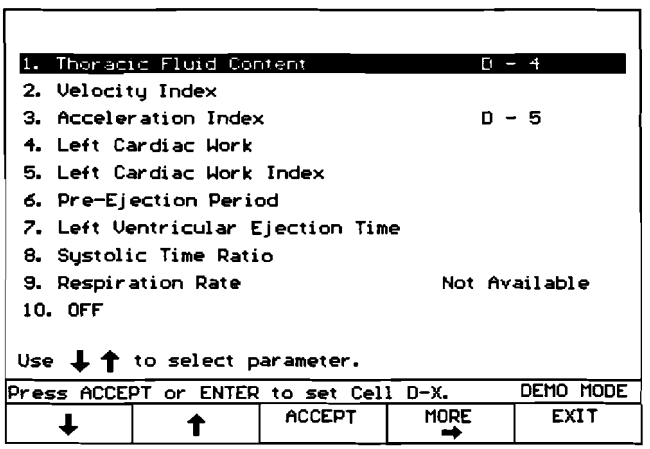


Figure 18. Hemodynamic Parameter Menu (1)

The Parameter that is currently displayed in Data Cell 4 will be highlighted and D-4 will be displayed to the right of the parameter. To deactivate D-4:

8) Press the '↓' softkey to select **'off'**. Press either the **'Accept'** softkey or the **'Enter'** hardkey. Press the **'Exit'** softkey, the user will be returned to the Monitoring Screen Configuration Screen (Figure 17).

9) Repeat steps 5 through 7 for Data Cell D-5. The following screen will be displayed:

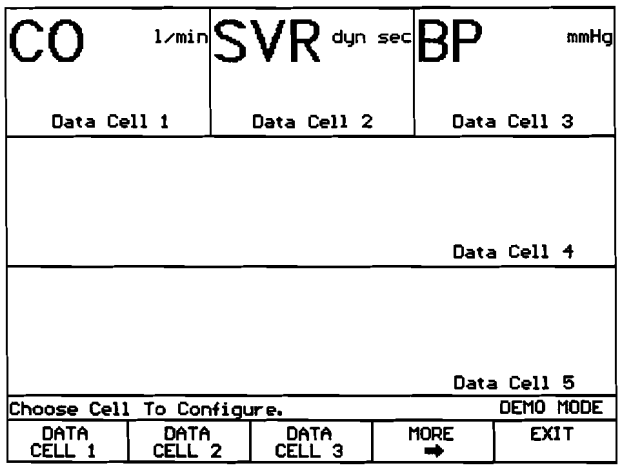


Figure 19. Monitoring Screen Cell Configuration Screen

The Graphic Cells expand to fill the screen.

10) Press the **'Exit'** softkey. The following screen will be displayed:

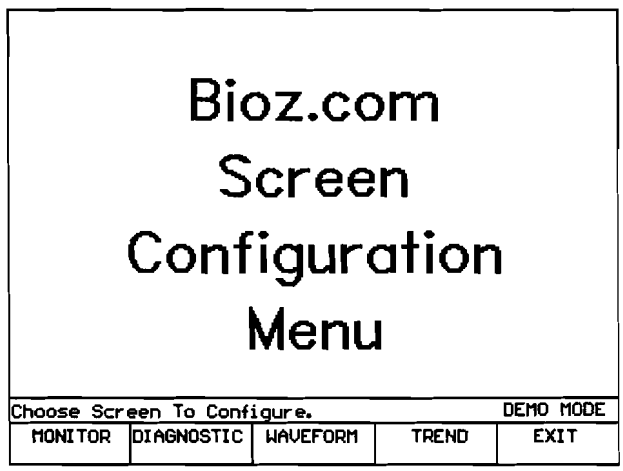


Figure 20. Screen Configuration Menu Screen

11) Press the **'Exit'** softkey again. The following screen will be displayed:

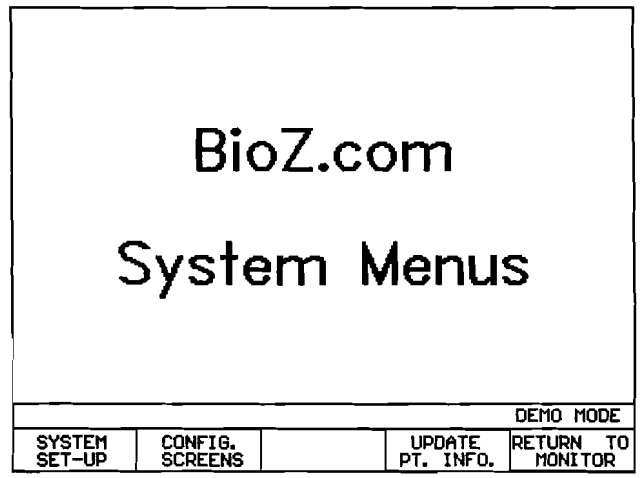


Figure 21. User Menu Screen

The BioZ.com® allows the User to define the default settings for many variables and/or parameters such as Alarms, Normal Ranges, Event Labels, and set Waveforms to Record. See section 8.1.1 for a detailed description.

12) Press the **'Return to Monitor'** softkey. The following screen will be displayed:

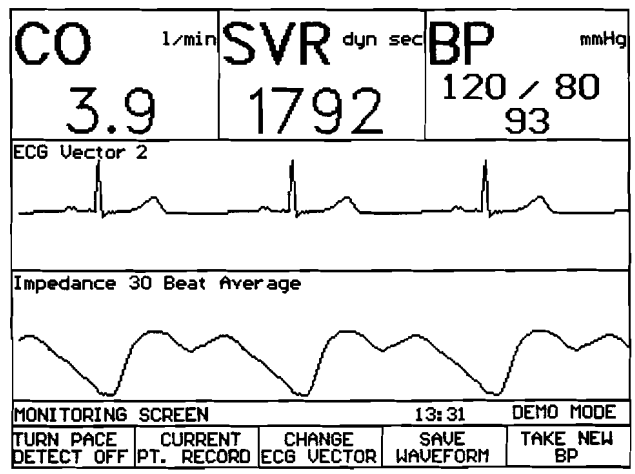


Figure 22. Patient Monitoring Screen (Demo Mode, Re-Configured)

To observe the five (5) different screens for displaying patient data during a monitoring session, the User can press either the **'Next Screen'** or **'Previous Screen'** hardkeys.

13) Press the **'Next Screen'** hardkey. The following screen will be displayed:

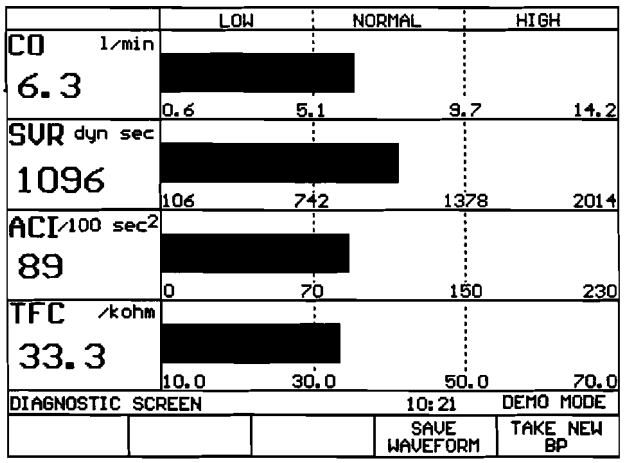


Figure 23. Diagnostic Screen (Demo Mode)

The Diagnostic screen will display up to four (4) of the available parameters at a time. The User may customize the Diagnostic Screen to display the parameters of their choice (see section 8.1.2). For an explanation of the Diagnostic Screen, see section 7.2.5.2.

14) Press the **'Next Screen'** hardkey. The following screen will be displayed:

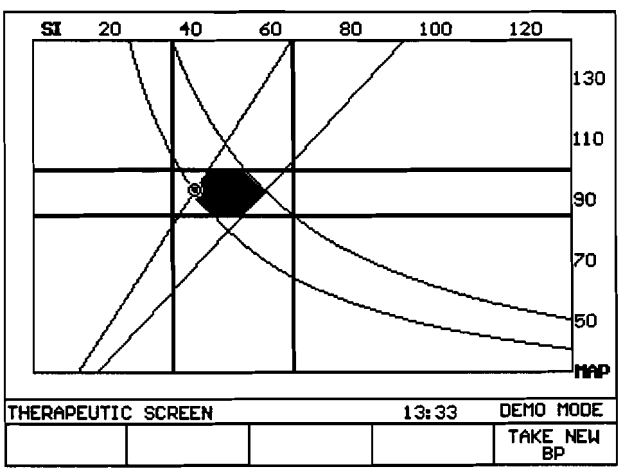


Figure 24. Therapeutic Screen (Demo Mode)

For an explanation of the Therapeutic Screen, see section 7.2.5.3.

15) Press the **'Next Screen'** hardkey. The following screen will be displayed:

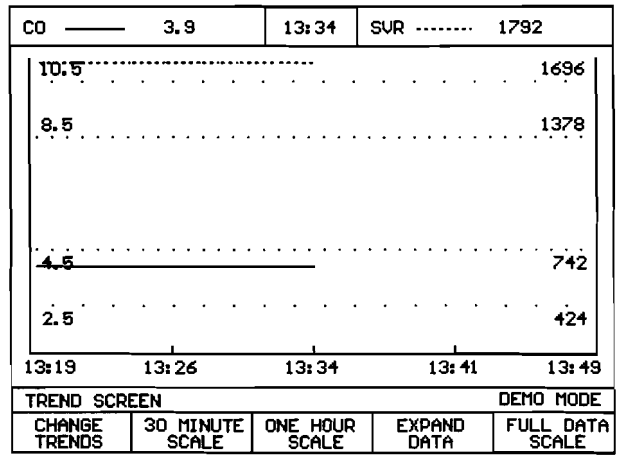


Figure 25. Trend Screen (Demo Mode)

The X-axis is auto scaled to display collected data. The minimum initial length is 30 minutes. The maximum display interval is 12 hours unless the User is in the **'Expanded Mode'**. The User has the ability to look at expanded segments of the monitoring session by choosing the appropriate softkeys. The User may also customize the parameters displayed on the Trend Screen by selecting the **'Change Trends'** softkey. For an explanation of the Trend Screen, see section 7.2.5.4.

16) Press the **'Next Screen'** hardkey. The following screen will be displayed:

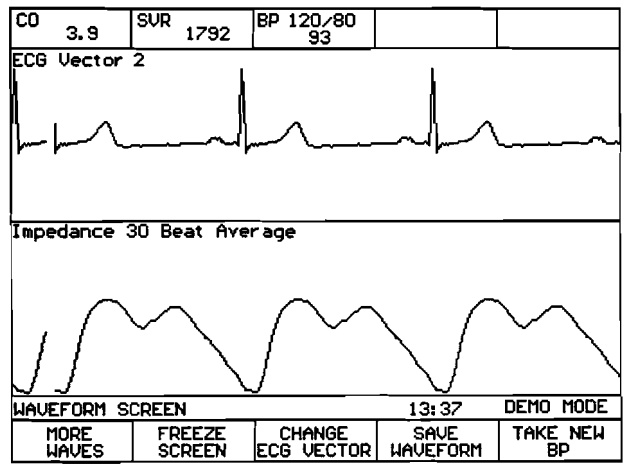


Figure 26. Waveform Screen (Demo Mode)

The Waveform Screen displays up to two (2) of the five (5) different waveforms produced or detected by the BioZ.com® at a time:

- Impedance Waveform (Delta Z)
- ECG Waveform (any of four vectors, see section 7.2.5.1)
- dZ/dt Waveform (first derivative of Delta Z)

- Pacer Impulse Waveform (impulse for each pacemaker trigger)
- Spike Enhancement Waveform (ECG and Pacemaker impulse)

The default waveforms for the Waveform Screen are the ECG and Delta Z waveforms. The **'More Waves'** softkey provides the User with the ability to view the alternate waveforms. See sections 7.2.5.5 and 8.1.2.4.

17) Press the **'Next Screen'** hardkey. The Monitoring Screen will be displayed (Figure 12).

6.4 Printing

The BioZ.com® provides the User with a variety of pre-formatted reports. The print command is active during all live monitoring sessions from the various patient monitoring screens as well as from the Review Record screens. To Print:

1) With the BioZ.com® turned off, connect the printer cable from the printer port on the rear panel of the BioZ.com® to a printer that uses Hewlett Packard PCL3 (or a more recent) communication language protocol.

Note: The Printer should be connected and turned on prior to turning on the BioZ.com®

Caution! When monitoring patients with indwelling catheters, the printer must be used with a Hospital/Medical grade power supply. Should you have questions or require clarification, please contact CardioDynamics Technical Service for more information.

2) Turn on the BioZ.com® and initiate a monitoring session as usual.

3) When ready to print, press the **'Print'** hardkey. The following screen will be displayed:

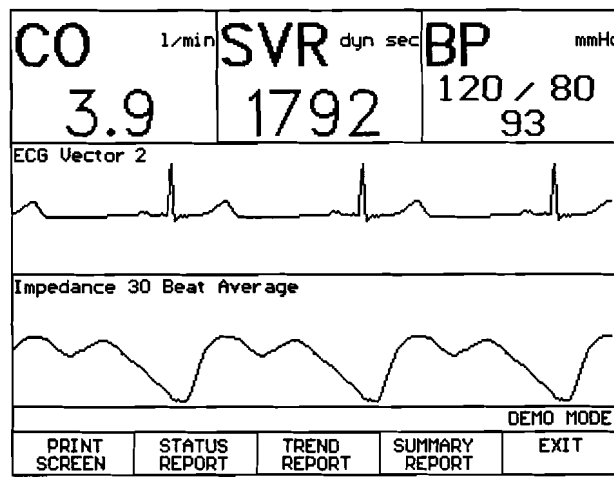


Figure 27. Print Option Screen (Demo Mode, Re-Configured)

Note: When the **'Print'** hardkey is pressed, the current screen display will not change; only the "soft keys" at the bottom of the screen will change.

The User may print any of the available pre-formatted reports. See section 8.2 for a detailed description on the types of reports available.

4) Press the appropriate softkey to print the desired report. The green Print LED will remain illuminated until the report has been transmitted to the printer.

6.5 Reviewing Patient Records

The BioZ.com® provides the User with access to patient records at all times. From the Welcome Screen the User may review patient records by pressing the **'Review Records'** softkey.

6.6 Exiting a Monitoring Session

1) Press the **'Stop Monitoring'** hardkey. The following screen will be displayed:

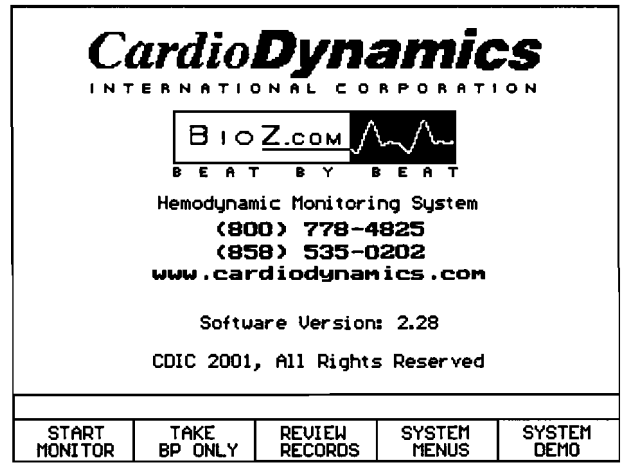


Figure 28. BioZ.com® Welcome Screen

The BioZ.com® is now ready for a "live' monitoring session. See **SECTION 5, QUICK-START INSTRUCTIONS** and **SECTIONS 7** and **8, "LIVE" PATIENT MONITORING** and **DETAILED DESCRIPTION.**

7 "LIVE" PATIENT MONITORING

A patient monitoring session is initiated from the Welcome Screen (Figure 28). The **'Start Monitor'** function is used to begin a "live" monitoring session.

The following sections will explain the steps necessary to monitor a patient.

7.1 Patient Preparation

The first step in beginning a monitoring session is to attach the patient ICG sensors.

7.1.1 ICG Sensors

To obtain accurate results with the BioZ.com®, high quality, ICG sensors with low skin-to-electrode impedance, proper spacing between transmitting and receiving sensors, and good adhesive properties are required. The ICG sensors distributed by CardioDynamics meet these requirements.

Only use sensors that have been recently removed from the sealed package. Sensors are single use disposable items. Check the package expiration date before use.

Note: The algorithm used to determine the stroke volume by Impedance Cardiography is dependent on the ICG Sensor conductive gel/electrode type, spatial relationship, and site placement. Use of non-CardioDynamics' approved ICG sensors will affect the ability of the BioZ.com® to determine the patient's hemodynamic parameters.

7.1.2 Skin Preparation

7.1.2.1 Wet Gel Sensors (BZ-200, 201)

1) Shave the hair over the sensor sites if necessary.

2) Thoroughly clean the skin areas with alcohol or electrode prep pad. Make sure that the skin is thoroughly dry before attaching sensors.

7.1.2.2 BioZtect™ Sensors (BZ-4550-01)

1) Shave the hair over the sensor sites if necessary.

2) 'Dry prep' the sensor sites by mildly abrading the skin with the perforation on the sensor backing.

7.1.3 ICG Sensor Application

7.1.3.1 Wet Gel Sensors (BZ-200, 201)

1) Check the expiration date on the sealed pouch prior to opening. Open the sealed pouch and remove the sensors. **Verify that the gel is still moist!**

2) Attach the reusable patient cable lead wires to the ICG sensors before removing the protective backing from the sensors. The black and white snap leads should be snapped onto one dual ICG

sensor, and the red and green snap leads should be snapped onto another dual ICG sensor. This should be repeated for both the left and right sets of patient cable lead-wires.

3) Remove the ICG sensor backing and apply each sensor, adhesive side down, to the proper sites indicated on the diagram (Figure 29).

4) Position the right and left (as indicated on the patient cable) dual ICG sensor patches with the white and black leads on the corresponding side of the neck. Use the root of the neck as a reference for vertically locating the white ICG sensor, with the black sensor being placed directly superior and inline with the ear lobe.

5) Position the right and left (as indicated on the patient cable) dual ICG sensor patches with the red and green leads on the corresponding side of the thorax along the mid-axillary line. Use the xiphoid process as a reference for placing the red ICG sensor, with the green sensor being placed directly inferior to the red sensor.

Caution! Locating the ICG Sensors incorrectly will adversely affect the ability of the BioZ.com® to measure and process the bioimpedance signal.

7.1.3.2 BioZtect™ Sensors (BZ-4550)

1) Check the expiration date on the sealed pouch prior to opening. Open the sealed pouch and remove the four dual sensor patches.

2) Prep the skin as listed above.

3) Remove the four dual sensor patches from the backing material and apply each sensor, adhesive side down, to the proper sites as indicated on the diagram (Figure 29) and the package label. The wide rectangular shaped end should be positioned closest to the heart. For the neck use the root of the neck as a reference for vertically locating the rectangular shaped detecting sensor with the corresponding circular shaped transmitting sensor being positioned directly superior and inline with the ear lobe. For the thorax use the xiphoid process as a reference for vertically locating the rectangular shaped detecting sensor with the corresponding circular shaped transmitting sensor being positioned directly inferior and along the mid-axillary line.

4) Connect the right and left (**with respect to the patient's right and left**) lead wires (as indicated on the patient cable yoke and individual lead wire connectors) to their respective dual sensor sites as follows:

- Depress the tab at the end of the connector, place the connector over the sensor stud and release the tab.

The lead wires must be attached as follows:

- Blue left and right lead wire connectors to the respective circular shaped transmitting sensors on the neck.

- Violet left and right lead wire connectors to the respective rectangular shaped detecting sensors on the neck.

- Green left and right lead wire connectors to the respective rectangular shaped detecting sensors on the thorax.

- Orange left and right lead wire connectors to the respective circular shaped transmitting sensors on the thorax.

Caution! Locating the ICG Sensors incorrectly will adversely affect the ability of the BioZ.com® to measure and process the bioimpedance signal.

Note: Both the neck and thorax ICG sensors must be positioned so that they are 180 degrees opposite each other. Should the patient have an invasive line, chest tube, etc. at the recommended locations, the ICG sensors may be rotated slightly as long as they remain 180 degrees opposite of each other.

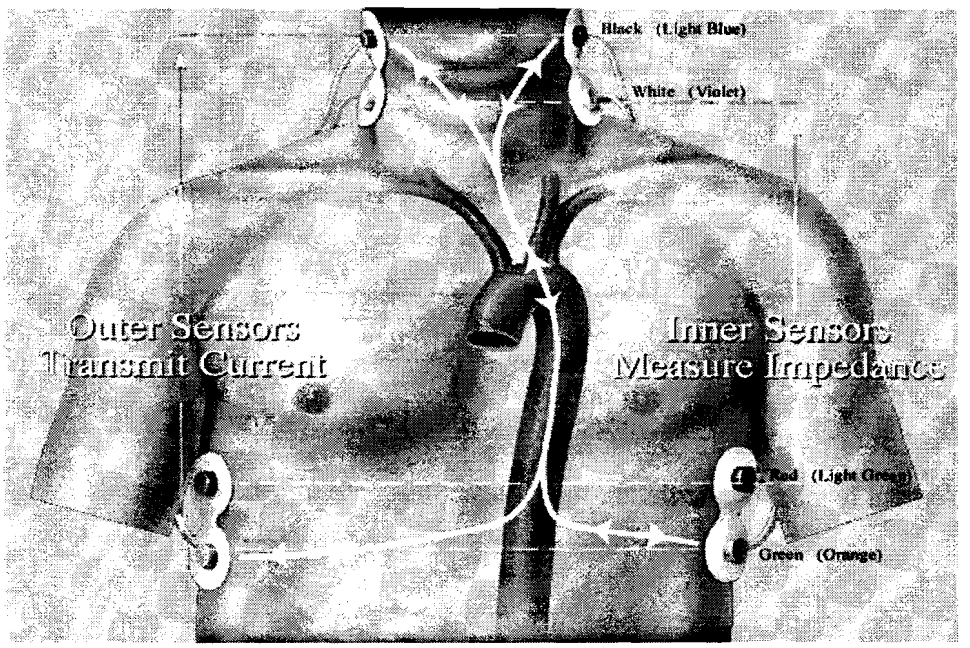


Figure 29. Impedance Cardiography Sensor Placement Diagram

7.2 Patient Monitoring

7.2.1 Blood Pressure without Starting ICG Monitoring Session

Note: This feature is only available with software version 2.28 and greater.

To obtain an independent blood pressure measurement without starting a monitoring session, at the Welcome Screen (Figure 28), press the **'Take BP Only'** softkey. The following screen will be displayed:

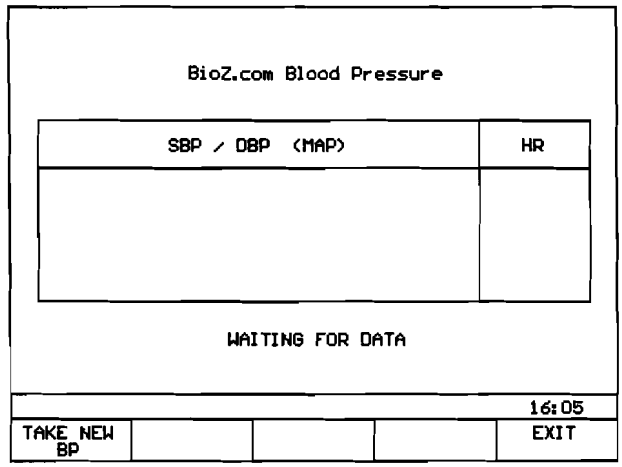


Figure 30. Independent Blood Pressure Screen

Once the measurement has been calculated, the following screen will be displayed:

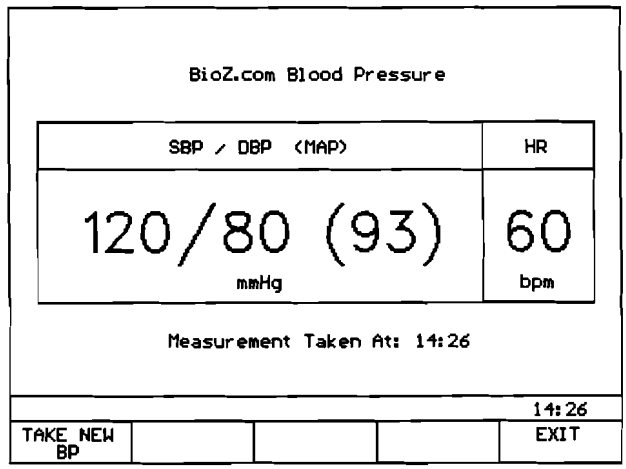


Figure 31. Blood Pressure Measurement Results Screen

Press the **'Exit'** softkey to return to the Welcome Screen. Press the **'Take New BP'** to repeat the blood pressure measurement.

7.2.2 ICG Monitoring Session

At the Welcome Screen (Figure 28), press the **'Start Monitor'** softkey. The Patient Data Entry screen will be displayed.

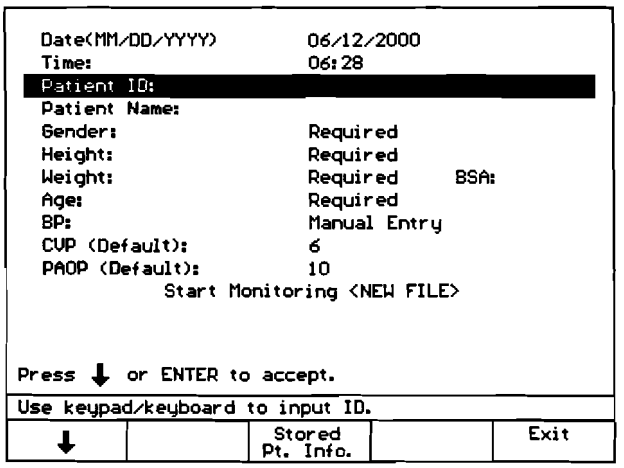


Figure 32. Patient Data Entry Screen

The Patient Data Entry Screen enables entry of all required patient information.

Note: If an incorrect entry is made, press the **'Clear'** hardkey and re-enter the correct value.

7.2.3 Softkeys

- '↓' Softkey – move highlight bar between fields.
- **'Stored Pt. Info'** softkey – allows the User to search for a previous monitoring session of the desired patient.

7.2.4 Patient Data Entry Fields

7.2.4.1 Patient ID

The Patient ID field is an optional field (i.e., information in this field is not required for the BioZ.com® to provide accurate hemodynamic parameters).

The Patient ID field accepts only numerical entries of up to nine digits.

- Data may be entered from either the numerical digit hardkeys on the BioZ.com® front panel or an external keyboard. If an incorrect value is entered, press the **'Clear'** hardkey to erase the entry and then re-enter the correct value.
- Press either the '↓' softkey or the **'Enter'** hardkey to advance to the Patient Name field.

- **Note:** If the Patient ID matches one that was previously entered into the BioZ.com®, the remaining data fields will automatically fill in with that patient's previously entered data. The User is then given the opportunity to make changes to the previously entered data prior to beginning the current monitoring session.

7.2.4.2 Patient Name

The Patient Name field is also an optional field.

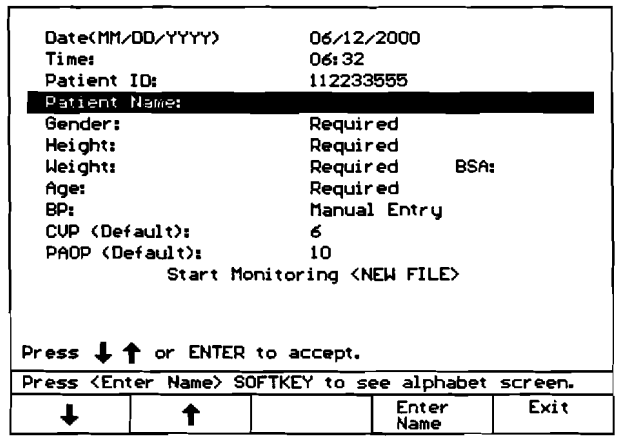


Figure 33. Patient Data Entry Screen

The Patient Name field accepts up to 25 characters.

- Press the **'Enter Name'** softkey to enter text into the Patient Name field. The Text Entry screen will be displayed:

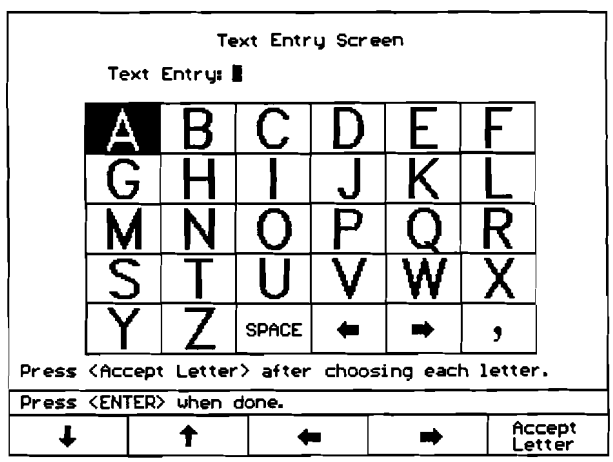

Text Entry Screen
Text Entry:
A B C D E F
G H I J K L
M N O P Q R
S T U V W X
Y Z SPACE ← → ,
Press (Accept Letter) after choosing each letter.
Press (ENTER) when done.
↓ ↑ ← → Accept Letter

Figure 34. Text Entry Screen

- If an external keyboard is attached, simply type in the desired alphanumeric entry. Press the **<Enter>** key on the keyboard when finished.

- If an external keyboard is not attached, press the appropriate arrow softkeys to highlight the desired character, press the **'Accept Letter'** softkey to enter the selected character into the Patient Name field. The ←, and → entries are for moving the cursor within the text string.

- Press the **'Clear'** hardkey if an incorrect entry was made.

- Press the **'Enter'** hardkey after the field is complete. The highlight bar will advance to the Gender field.

Note: If the Patient ID and Name fields are left blank, the User will only be able to identify the file by the date and time of the session. While both of these fields are optional, it is beneficial to place an entry in at least one of the fields.

7.2.4.3 Gender

The BioZ.com® requires the gender of the patient to accurately determine their hemodynamic status.

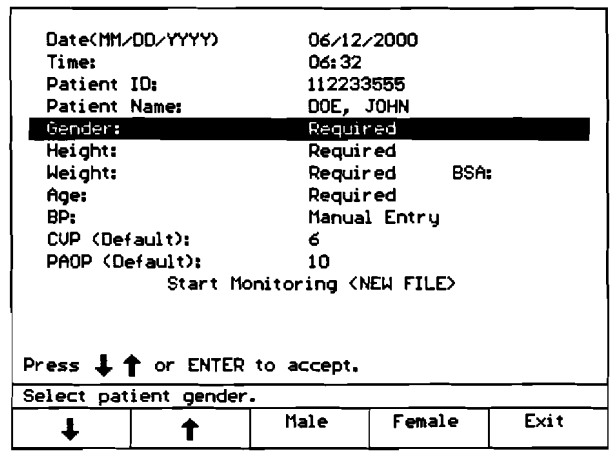


Figure 35. Patient Data Entry Screen

- Press the appropriate **'Male'** or **'Female'** softkey. The highlight bar will be advanced to the Height field.

7.2.4.4 Height

The Height field is required for accurate processing of the patient's hemodynamic status. The accuracy of some of the data provided by the BioZ.com® may be compromised on persons under 120cm (48in) or over 230cm (90in) in height (see section 2.2, **Precautions**).

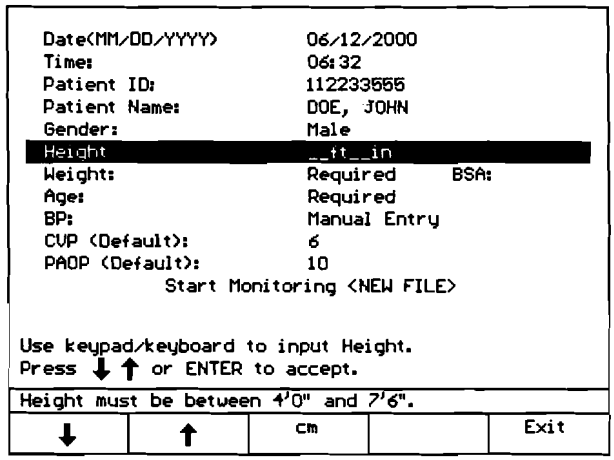


Figure 36. Patient Data Entry Screen

- Press the appropriate numerical hardkeys in order to enter the 'ft' and 'in' data in the respective fields, or press the **'cm'** softkey to enter the height in centimeters. Press the **'Enter'** or the '↓' key. The highlight bar will be advanced to the Weight field

- **Note:** If an entry greater than eleven (11) is entered into the 'in' field, press **'Clear'** and re-enter the correct value; otherwise the BioZ.com® will convert the entry to it's equivalent height in feet and inches. For example, if 5 feet 13 inches is entered into the 'ft' and 'in' fields respectively, the BioZ.com® will convert the entry to 6 feet 1 inch. Also, if the value entered is out of the required range, as displayed on the screen, an error screen will be displayed prior to beginning the monitoring session (Figure 45).

7.2.4.5 Weight

The Weight field is required for accurate processing of the patient's hemodynamic status. The accuracy of some of the data provided by the BioZ.com® may be compromised on persons under 30 kg (67 lbs) or over 155 kg (341 lbs) in weight (see section 2.2, **Precautions**).

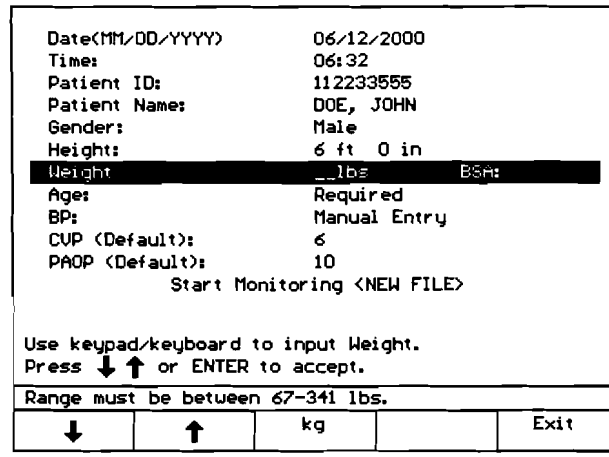


Figure 37. Patient Data Entry Screen

- Press the appropriate numerical keys in order to enter the patient's correct weight (in lbs.), or press the **'kg'** softkey to enter the correct weight in kg. Press the **'Enter'** or the '↓' key, the highlight bar will be advanced to the Age field.

- **Note:** If the value entered is out of the required range, as displayed on the screen, the "Data Out of Range" screen (Figure 45) will be displayed prior to beginning the monitoring session.

- **Note:** The Body Surface Area (BSA) will be calculated and displayed after the weight has been entered.

7.2.4.6 Age

The Age field is required for accurate processing of the patient's hemodynamic status.

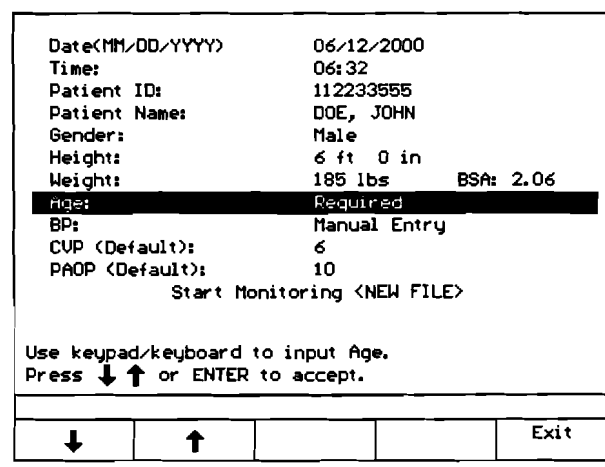


Figure 38. Patient Data Entry Screen

- Press the appropriate numerical keys in order to enter the patient's correct age. Press the **'Enter'** or the '↓' key, the highlight bar will be advanced to the Blood Pressure field.

7.2.4.7 Blood Pressure

The Blood Pressure field is required for accurate processing of the patient's hemodynamic status. The accuracy of some of the data provided by the BioZ.com® may be compromised on persons whose MAP is less than 30 mmHg or greater than 220 mmHg.

The BioZ.com® allows the User to select one of two methods for obtaining the patient's blood pressure:

- BioZ.com® NIBP cuff (optional feature, not available on all models)
- Manual Entry

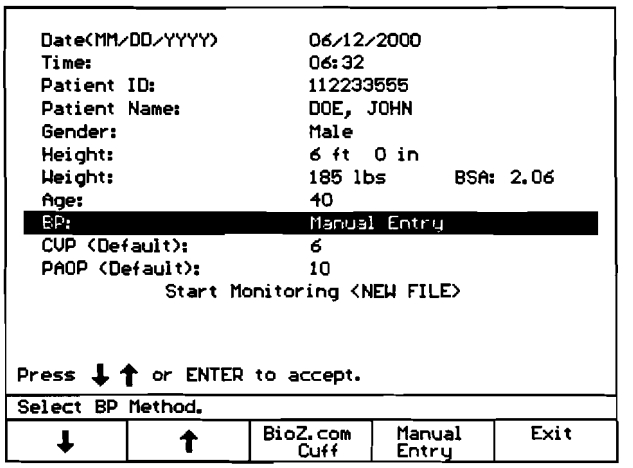


Figure 39. Patient Data Entry Screen

7.2.4.8 BioZ.com® Cuff (optional feature, not available on all models)

The BioZ.com® NIBP module utilizes the Oscillometric method in determining blood pressure values. The oscillometric method measures the pressure pulse within the cuff in incremental steps. This pressure pulse has a maximum value of approximately 1 mmHg that occurs at the MAP. A sophisticated algorithm is then applied to plot the Oscillometric Envelope of pulse pressure measurements vs. cuff pressure measurements. The cuff pressure at which the peak pressure pulse occurs is the MAP. The diastolic and systolic values are the cuff pressures that intersect at pre-determined percentages (not fixed percentages, but percentages based on the measured MAP and pressure pulse amplitude) of the peak pulse pressure.

The shape of an actual patient Oscillometric Envelope varies from measurement-to-measurement and from individual-to-individual. Therefore it is quite possible to have different systolic and diastolic pressures for the same measured MAP as well as different MAPs for the same systolic and diastolic pressures.

To use the BioZ.com® NIBP cuff:

- Wrap the Cuff around the patient's upper arm (observe the precautions listed below). Ensure that the cuff is positioned so that the arrow aligns with the patient's artery.

- Connect the coiled inflation tube to the NIBP Port on the front panel of the BioZ.com®.
- Press the **'BioZ.com Cuff'** softkey if that is the desired method of blood pressure determination.

Once the monitoring session begins, the BioZ.com® will automatically operate the blood pressure cuff to obtain the measurement.

Note: In order to obtain an accurate blood pressure measurement and to ensure the safety of the patient, it is essential that the following precautions be observed:

- **Use only the blood pressure cuff provided with the device.**
- **Use the proper size cuff for the patient's arm.**
- **Ensure that the cuff is evenly and snugly wrapped around the patient's arm.**
- **Ensure that the bladder within the cuff is not folded.**
- **Ensure that all connections are tight so as to prevent leakage.**
- **While making blood pressure measurements be sure to avoid any compression or restriction of the pressure tube leading to the cuff.**
- **The operator is advised to observe directly that inflation of the cuff does not result in prolonged impairment to the patient's circulation.**
- **The patient's arm should remain relaxed and still while the blood pressure cuff is inflating and deflating.**

The BioZ.com® will update the patient's blood pressure every five (5) minutes. The five-minute interval may be customized to meet the User's requirements. See section 8.1.1.3 for a detailed description.

7.2.4.9 Manual Entry

When **'Manual Entry'** is the source for entering the SBP and DBP the BioZ.com® will calculate a MAP using the following algorithm:

If [(SBP-DBP)/DBP] < 0.5 Then KP = 0.333

If [(SBP-DBP)/DBP] > 1.0 Then KP = 0.25

$KP = 0.333 - \{[(SBP - DBP)/DBP) - 0.5]/6\}$

$MAP = DBP + [KP\ (SBP-DBP)]$

For example:

If a BP = 150/65 is entered manually into the BioZ.com® the calculated MAP would be:

(150-65)/65 = 1.31, therefore, KP = 0.25 and MAP = 65 + [0.25(150-65)] = 86.25

In the example above, the simple equation of MAP = DBP + (SBP – DBP)/3, the MAP would equal 93.33 instead of 86.25

Press the **'Manual Entry'** softkey. The following screen will be displayed:

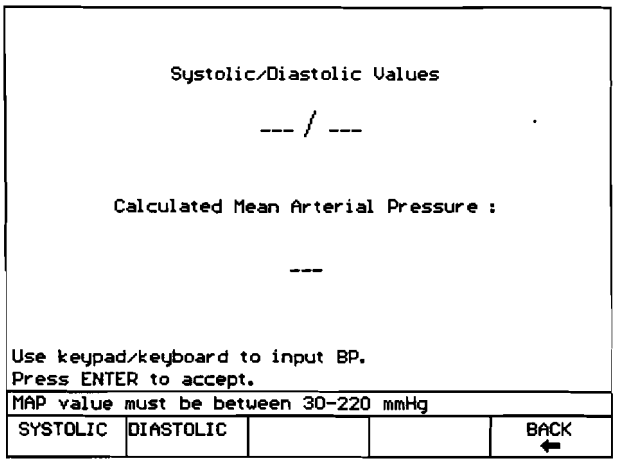


Figure 40. Manual Blood Pressure Entry Screen

Press the appropriate numerical keys in order to enter the correct Systolic and Diastolic pressures. Press the **'Enter'** hardkey. If an incorrect entry is made, press the **'Clear'** hardkey and re-enter the correct value. If the calculated MAP is NOT within the allowed range, the "Data Out of Range" message screen (Figure 41) will be displayed, otherwise, the highlight bar will be advanced to the CVP field.

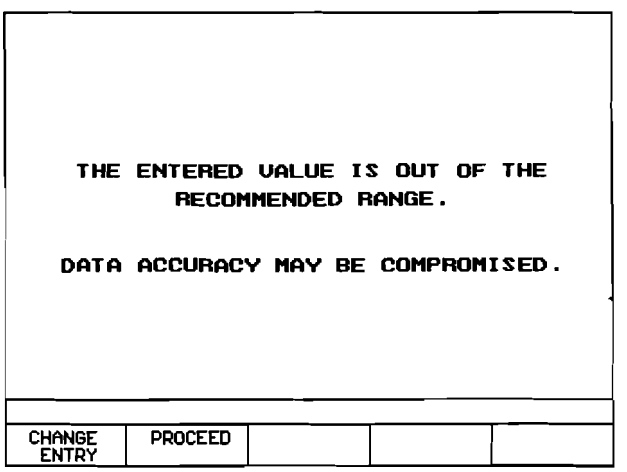


Figure 41. Blood Pressure Out of Range Screen

7.2.4.10 Central Venous Pressure

The BioZ.com® allows the User to enter the patient's actual central venous pressure (CVP). If this value is not known, the BioZ.com® has a default setting of 6 mmHg (see section 8.1.1.3 to change the default setting).

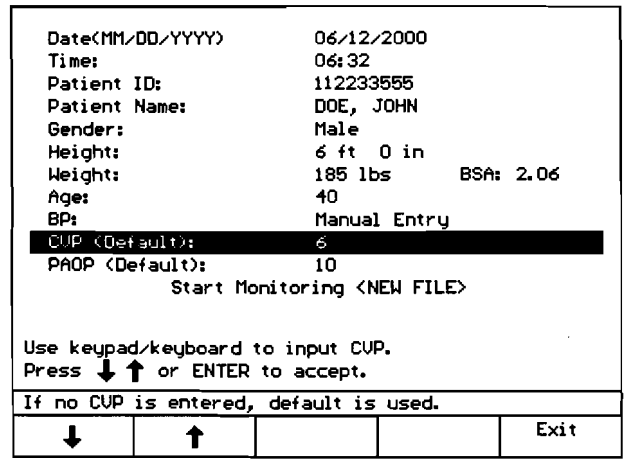


Figure 42. Patient Data Entry Screen

- Use either the numerical hardkeys on the BioZ.com® face or the external keyboard to enter the current value or press the **'Enter'** or the '↓' key to accept the default value. The highlight bar will be advanced to the PAOP field.

Note: If an incorrect entry is made, press the **'Clear'** hardkey and re-enter the correct value.

7.2.4.11 Pulmonary Artery Occluded (Wedge) Pressure

The BioZ.com® allows the User to enter the patient's actual PAOP. If this value is not known, the BioZ.com® has a default setting of 10mmHg (see section 8.1.1.3 to change the default setting).

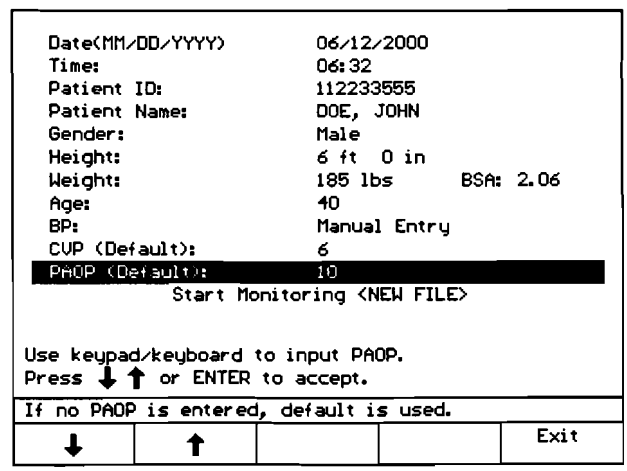


Figure 43. Patient Data Entry Screen

- Use either the numerical hardkeys on the BioZ.com® face or the external keyboard to enter the current value or press the **'Enter'** or the '↓' key to accept the default value. The User will be prompted to "Start Monitoring".

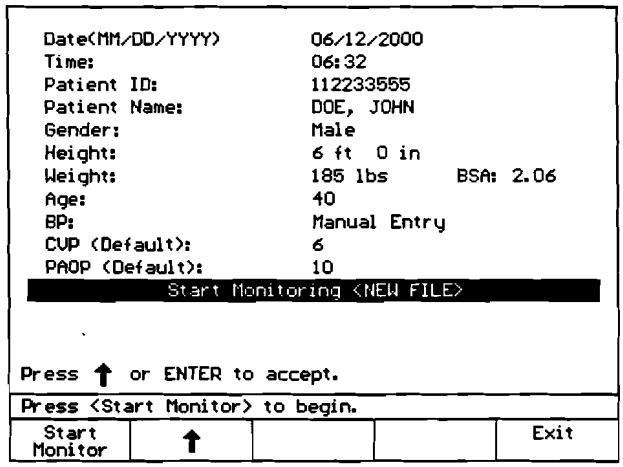


Figure 44. Patient Data Entry Screen

- Press the **'Start Monitor'** softkey to begin the monitoring session.

Note: If any of the below fields are out of the recommended range, the following screen will be displayed:

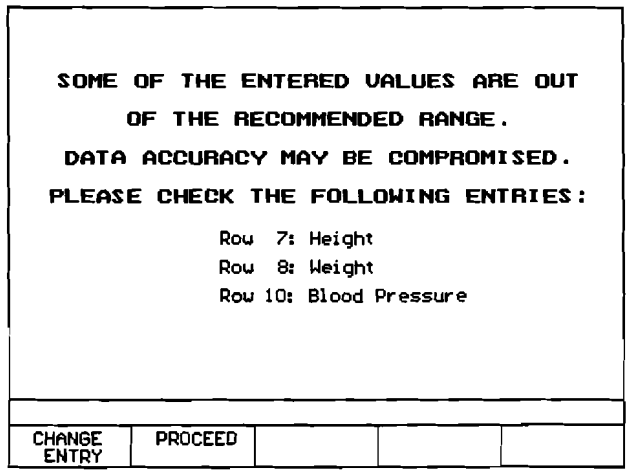


Figure 45. Data Out of Range Screen

7.2.5 Patient Monitoring Screens

When monitoring a patient, the BioZ.com® provides five (5) basic screens for presenting the various hemodynamic parameters:

- Monitoring Screen
- Diagnostic Screen
- Therapeutic Screen
- Trend Screen
- Waveform Screen

There are eight common features to the patient monitoring screens that are controlled by the following eight hardkeys (section 4.2.2):

1) The **'Menu'** hardkey allows the User access to the system default settings while monitoring a patient.

2) The **'Previous Screen'** hardkey cycles the User through the five patient monitoring screens in reverse direction.

3) The **'Next Screen'** hardkey cycles the User through the five patient monitoring screens in the forward direction.

4) Pressing the **'Event'** hardkey allows the User to select a pre-defined text label, which will be stored at the selected time point in the patient's record. This text label will be visible on printed reports.

5) The **'Stop Monitoring'** hardkey will end the monitoring session and return the User to the Welcome screen.

   Note: The **'Stop Monitoring'** hardkey is inactive if the BioZ.com® blood pressure cuff is inflated.

6) The **'Print'** key allows the User to print any of the reports provided by the BioZ.com®.

7) The **'Alarm On/Off'** hardkey allows the User to enable/disable the alarm function of the BioZ.com®.

8) The **'Reset Alarm'** hardkey allows the User to silence an audible alarm signal and reset the alarm.

7.2.5.1 Monitoring Screen

Note: The setting/configuration of the Data and Graphic Display cells for the Monitoring Screen depicted in Figure 46 may be different for your device.

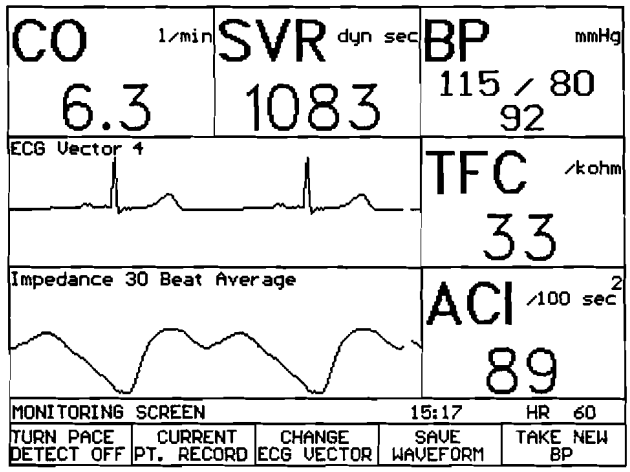


Figure 46. Monitoring Screen (Live Mode)

The Monitoring Screen consists of a maximum of five (5) data display cells and two (2) graphic display cells. The BioZ.com® provides the User with the ability to customize the number of active data cells as well as the parameters displayed by those cells (see section 8.1.2).

- The **'Turn Pace Detect Off/On'** softkey allows the user to deactivate/activate the pacemaker detector circuit.

  By default, the Pacemaker Detect Circuit is activated each time you begin a monitoring session. There is no need for the User to change this setting.

- The **'Current Pt. Record'** softkey allows the User to access the patient data record for the patient currently being monitored.

- The **'Change ECG Vector'** softkey toggles through four available ECG vectors detected by the BioZ.com®: 1) a 'transthoracic' configuration (across the superior thorax sensors), 2) modified Lead II, 3) modified Lead III, 4) a 'cross torso' configuration (from the left inferior neck sensor to the right superior thorax sensor).

  The default ECG presentation is the ''Modified Lead II' configuration (vector 2). The QRS signal should have sufficient magnitude. To select the best R-wave recognition setting, the User may press the **'Change ECG Vector'** softkey to rotate through the four ECG presentations. The User should wait at least 30 seconds after each time the **'Change ECG Vector'** softkey is pressed so that the BioZ.com® may update the data.

- The **'Save Waveform'** softkey saves the previous 26 seconds of patient waveforms.

The **'Take New BP'** softkey performs one of two functions depending on the mode of blood pressure determination:

1) Pressing the **'Take New BP'** softkey will trigger the optional BioZ.com® blood pressure measuring cuff to inflate/deflate so as to obtain the blood pressure (if the BioZ.com® is equipped with this option).

2) If the source of blood pressure readings is by manual entry, pressing the **'Take New BP'** softkey will display the following pop-up menu:

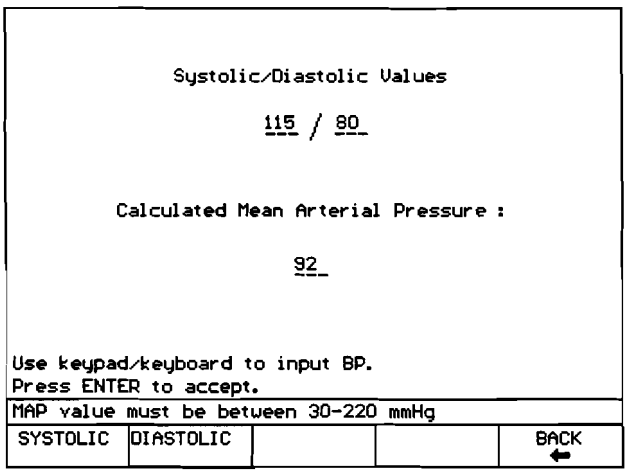


Figure 47. Manual Blood Pressure Entry Screen (Live Mode)

- Press the **'Systolic/Diastolic'** softkeys to place the cursor in the desired field.
- Press the **'Clear'** hardkey to clear the current entry.
- Use the numerical hardkeys to enter the correct blood pressure.
- Press the **'Enter'** hardkey to accept the entry and return to the screen of entry.

Note: If the calculated MAP is out of range, the User will receive the following message:

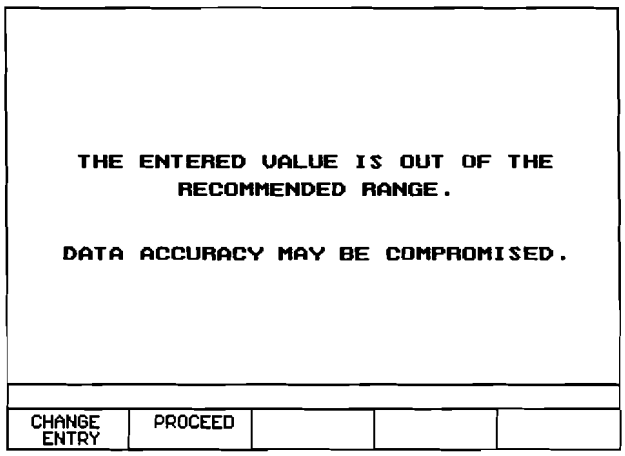


Figure 48. Data Out of Range Screen

- Select either the **'Change Entry'** softkey to re-enter the correct value, or the **'Proceed'** softkey to return to the Monitoring Screen.

To advance to another patient monitoring screen, press either the **'Next Screen'** or **'Previous Screen'** hardkeys.

7.2.5.2 Patient Diagnostic Screen

The Patient Diagnostic Screen will display up to four of the hemodynamic parameters provided by the BioZ.com® in a horizontal bar graph display. The Diagnostic screen is divided into three sections in order to denote the low, normal, and high ranges for the displayed parameters.

Note: See section 8.1.1.2 to select the parameters and normal ranges of operation.

The Diagnostic Screen is accessed by pressing the **'Next Screen'** hardkey from the patient Monitoring Screen (Figure 46) or the **'Previous Screen'** hardkey from the patient Therapeutic Screen (Figure 50).

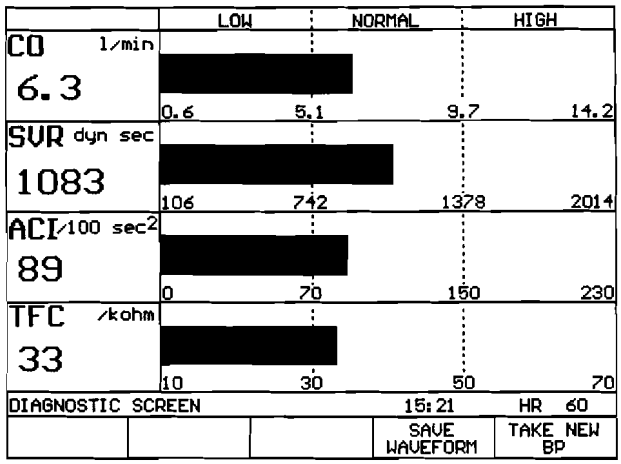


Figure 49. Diagnostic Screen (Live Mode)

See section 7.2.5.1, Patient Monitoring Screen, for an explanation of the **'Take New BP'** softkey.

7.2.5.3 Patient Therapeutic Screen

The hemodynamic status of a patient is displayed graphically (Figure 50) on an integrated screen with Stroke Index (SI) on the horizontal axis and Mean Arterial Pressure (MAP) on the vertical axis.

The shaded region represents the therapeutic target and is determined by the pre-defined normal ranges of SI and MAP. The underlying hemodynamic conditions reflected in the boundaries of the shaded region are defined as normotension, normodynamic, normo-strokework, and normovasoactivity conditions.

Note: The shape of the shaded region varies depending on the normal ranges/default values defined by the User.

The hemodynamic status variations of tension and dynamics are defined[1] as:

Normotension (represented by the horizontal lines)

$84 < MAP < 100$ mm Hg

The dynamic condition is represented by the circulation/beat [i.e., Stroke Index (SI)]

Normodynamic (represented by the vertical lines)

$35 < SI < 65$ ml/m^2

Left Stroke Work Index (LSWI) hyperbola curves on the Therapeutic Screen are proportional to the mean myocardial oxygen consumption per beat. Myocardial energy production takes place during mechanical systole and corresponds to the forces utilized to shorten myocardial fibers (i.e., the contractile force of the myocardial fibers). LSWI is dependent on both pre-load and contractility.

Normo-strokework (related to a combination of both pre-load and contractility for the predefined normotensive state)

47.2 g x m/m^2 $< LSWI <$ 70.8 g x m/m^2

Vasoactivity is determined on a beat-by-beat basis (Stroke Systemic Vascular Resistance Index, SSRI).

$SSRI = (MAP - CVP) * 80 / SI$

Normovasoactivity is defined as the ideal SSRI as determined by the ideal SI (50 mL/m^2) and MAP (93 mmHg).

Normovasoactivity is represented by the diagonal lines on the screen. The diagonal lines are defined as ideal SSRI $\pm$ 20%. The area to the left of the diagonal lines indicates Vasoconstriction. The area to the right of the diagonal lines indicates Vasodilation.

---

1 Hurst JW, ed. *The Heart.* 5th ed. New York: McGraw-Hill, 1982:93.

The Therapeutic screen is accessed by pressing the **'Next Screen'** hardkey from the patient Diagnostic Screen (Figure 49) or the **'Previous Screen'** hardkey from the patient Trend Screen (Figure 51).

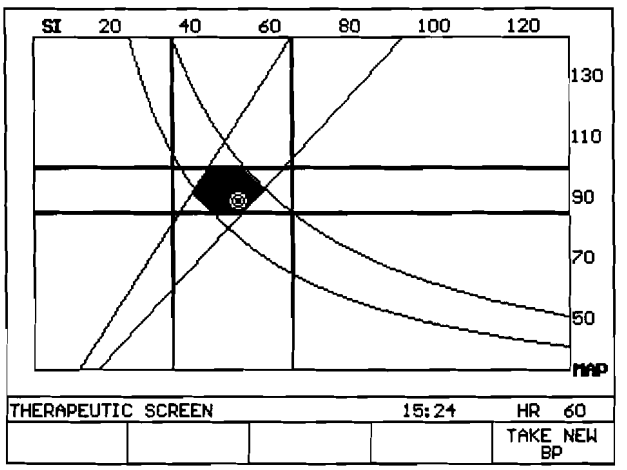


Figure 50. Therapeutic Screen (Live Mode)

The patient's status in relation to SI and MAP is displayed as a circle. This circle moves as the patient's hemodynamic status changes. The underlying hemodynamic conditions that affect the SI and MAP [the location of the circle (i.e., the patient's status)] are pre-load, contractility, and after-load (vasoactivity). There are multiple possible combinations of these conditions, depending on the patient's underlying variables.

There are nine classifications of hemodynamic status:

Table 1. Hemodynamic Status Classifications

Tension Status	Dynamic Status
Hypertensive	Hyperdynamic
	Normodynamic
	Hypodynamic
Normotensive	Hyperdynamic
	Normodynamic
	Hypodynamic
Hypotensive	Hyperdynamic
	Normodynamic
	Hypodynamic

7.2.5.4 Patient Trend Screen

The patient Trend Screen provides the User with the ability to view trending plots for up to two of the hemodynamic parameters provided by the BioZ.com® (see section 8.1.2.3 for selecting the trending parameters). The Trend Screen provides the User with a graphical representation of the various hemodynamic parameters over time; thereby allowing the User to quickly evaluate the effectiveness of any treatment and/or therapy given to the patient.

The Trend Screen is accessed by either pressing the **'Next Screen'** hardkey from the patient Therapeutic Screen (Figure 50) or the **'Previous Screen'** hardkey from the patient Waveform Screen (Figure 54).

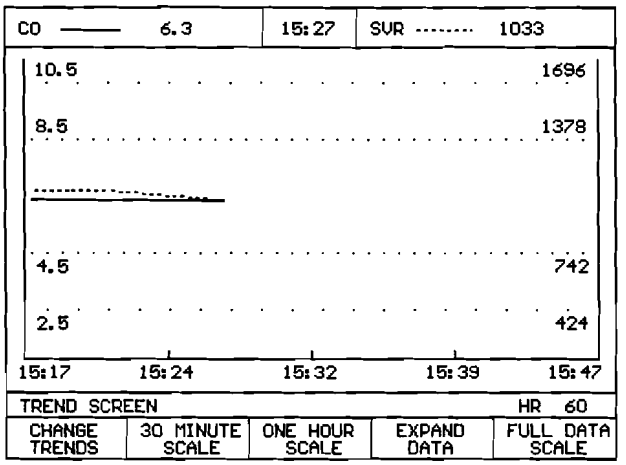


Figure 51. Trend Screen (Live Mode)

During a monitoring session, the Trend Screen is auto-scaled along the x-axis to provide a display of up to 12 hours of the most recent recorded patient data collected within the current monitoring session (the initial scale is set at 30 minutes). Softkeys at the bottom of the screen provide the User with the ability to select, isolate and expand desired timeframes of the monitoring session for a more detailed view.

Note: The Trend Screen plots (and updates) based on the data that has been saved in the Patient's file. The Trend Screen does NOT plot each screen update. For example, if the Auto Data Save Interval is set at 15 minutes and the Display Update is set at 10 beats, the Trend screen will not plot a trend line for the first 15 minutes and will only update every 15 minutes thereafter.

- The **'30 Minute Scale'** softkey changes the scale to 30 minutes and displays the most recent 30 minutes of data for the selected parameter(s).

- The **'One Hour Scale'** softkey changes the scale to 1 hour and displays the most recent 1 hour of data for the selected parameter(s).

- The **'Full Data Scale'** softkey will reset the scale to a value up to 12 hours depending on the length of the monitoring session.

- The **'Expand Data'** softkey displays the trend data in an auto scaled format and provides the User with the ability to "zoom in" for a more detailed view of a particular time frame.

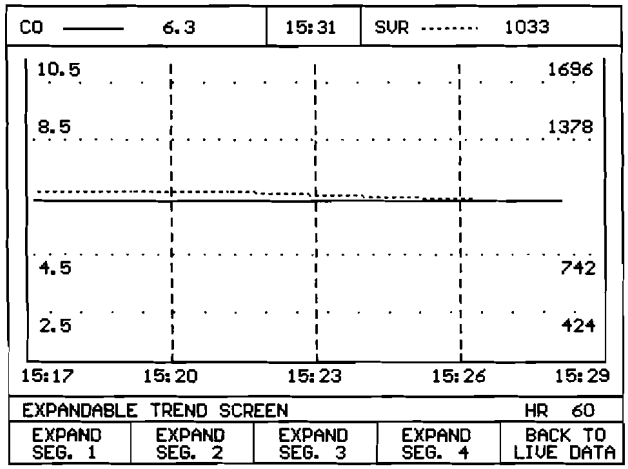


Figure 52. Expandable Trend Screen (Live Mode)

The **'Expand Seg.'** softkeys available to the User on the above screen allow the trending data to be divided and expanded into segments for easier viewing.

Note: The minimum viewable segment length is 3 minutes.

- Press the **'Back to Live Data'** softkey to return to the updated Trend Screen (the scale will be the same as when entering **'Full Data Scale'** function).

- The **'Change Trends'** softkey allows the User to view other waveforms besides the default setting.

- Press the **'Change Trends'** softkey to select other waveforms for viewing. The Trend Screen Set-up screen will be displayed:

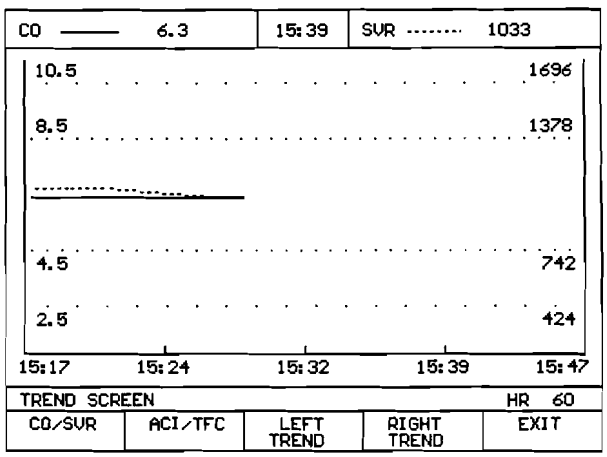


Figure 53. Trend Screen Set-Up Screen (Live Mode)

- The two softkeys on the furthest left of the screen show the two default trending parameter settings (see section 8.1.2).

- Pressing the **'Left Trend'** and **'Right Trend'** softkeys allows the User to select the parameter that they wish to display during that monitoring session only. Once the monitoring session has ceased the default left/right trends will be displayed on subsequent monitoring sessions.

7.2.5.5 Waveform Screen

The Waveform Screen is similar to the Monitoring Screen. There are two graphics display cells for displaying up to two of the five waveforms provided by the BioZ.com® as well as five data display cells. The data display cells are the same as provided on the Monitoring Screen, the difference being that the User has no control over the data display cells from the Waveform Screen. The advantage of this screen is that the User can cycle between all five waveforms at the press of a key.

The Waveform screen is accessed by pressing the **'Next Screen'** hardkey from the patient Trend Screen (Figure 51) or the **'Previous Screen'** hardkey from the patient Monitoring Screen (Figure 46).

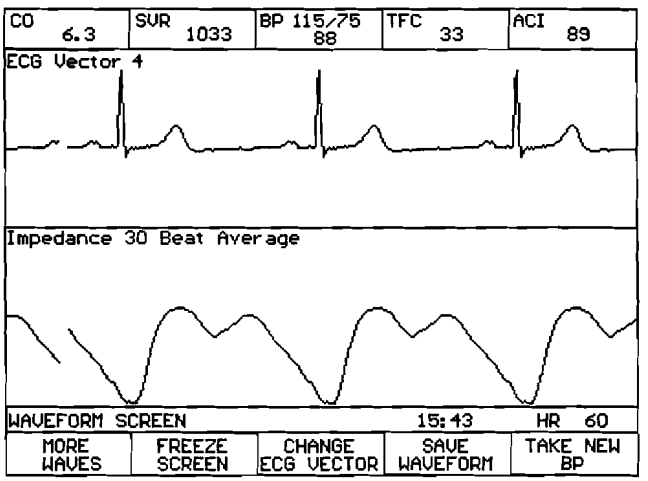


Figure 54. Waveform Screen (Live Mode)

Note: The **'Change ECG Vector'** softkey is only displayed if the ECG waveform is displayed.

The **'More Waves'** function allows the User to cycle through the following waveforms:

- Impedance Waveform (delta Z)
- ECG Waveform
- dZ/dt Waveform
- Pacer Impulse Waveform
- Spike Enhancement Waveform

- The **'(Un)Freeze Screen'** softkey allows the User to unfreeze/freeze the screen display to better view the waveforms.

- The **'Change ECG Vector'** softkey toggles through the four available ECG vectors detected by the BioZ.com® (see section 7.2.5.1).

- The **'Take New BP'** softkey triggers the BioZ.com® cuff blood pressure monitoring device or the User is prompted to manually enter the blood pressure.

- The **'Save Waveform'** softkey saves waveforms for exporting to another PC.

Press the **'Next Screen'** hardkey to return to the Monitoring Screen.

8. DETAILED DESCRIPTION

8.1. Welcome Screen

The Welcome Screen is the first screen displayed when the BioZ.com® is powered on and when the **'Stop Monitoring'** key is pressed during a patient monitoring session. The Welcome Screen represents the starting point for the User when operating the BioZ.com®. From the Welcome Screen the User is able to begin a monitoring session, review patient records, simulate a monitoring session, and/or access the various User menu functions.

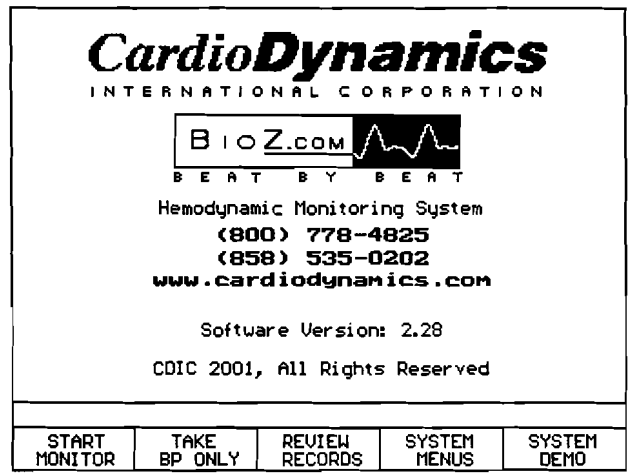


Figure 55. Welcome Screen

The BioZ.com® is equipped with many features that provide the User with the ability to customize the settings and configurations of the various patient monitoring screens. All system functions and settings are accessed through the BioZ.com® User Menus. The BioZ.com® User Menus can be accessed from the Welcome Screen prior to beginning a patient monitoring session, or from the various patient monitoring screens during a patient monitoring session. Thus, the User need not exit from a patient monitoring session in order to customize the settings/configuration of the BioZ.com®.

To access the BioZ.com® User Menus from the Welcome Screen, press either the **'System Menus'** softkey or the **'Menu'** hardkey. From any of the patient Monitoring Screens, press the **'Menu'** hardkey. The User Menu Screen will be displayed.

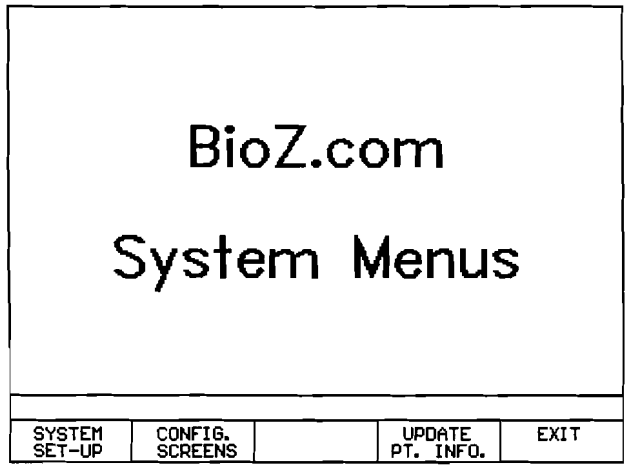


Figure 56. BioZ.com® User Menu Screen

Note: The right-most softkey will be **'Return to Monitor'** if accessed during a patient monitoring session or **'Exit'** if coming from the Welcome Screen.

The BioZ.com® organizes the User Menus into three (3) main areas:

- System Set-up
- Configure Screens
- Update Patient Information

8.1.1 System Set-up

The BioZ.com® Set-Up menu provides the User with the ability to modify a variety of the BioZ.com's default settings. By pressing the **'System Set-up'** key, the User has access to the following settings/functions:

- Set up various parameter ***alarm conditions***
- Define the ***normal range(s)*** for the hemodynamic parameters as displayed on the Diagnostic Screen
- Set ***system defaults*** for patient data entry screen
- Set User ***password***
- Define which ***waveforms*** to record
- Define ***event labels***

- Enter ***facility name***
- Select the ***language of operation***
- Configure the ***custom hemodynamic status report***

From the BioZ.com® User Menu Screen, press the **'System Set-up'** key. The following screen will be displayed:

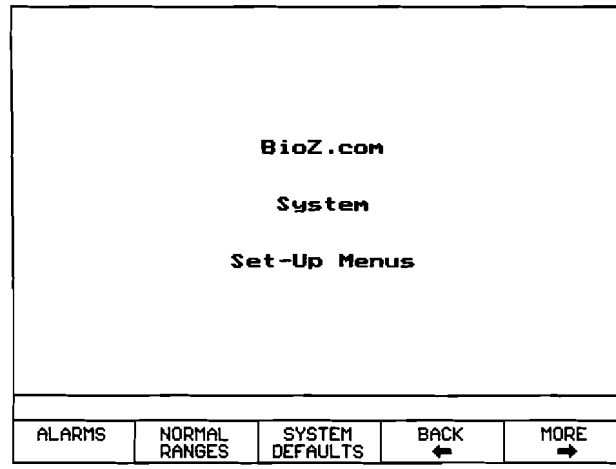


Figure 57. BioZ.com® Set-Up Menu Screen

8.1.1.1 Alarms

The BioZ.com® provides both an audible and visual alarm for the following parameters:

- Heart Rate (HR)
- Thoracic Fluid Content (TFC)
- Cardiac Index (CI)

The alarm system is active during all monitoring sessions, including Demo Mode sessions. The User can deactivate the alarm circuit by pressing the **'Alarm on/off'** hardkey. An LED next to the hard key will turn green when the alarm system is enabled (monitoring has begun). The LED will automatically turn amber (red on some units) if a User stops patient monitoring (live or Demo Mode), presses the Alarm On/Off hard key, or enters a message screen where the alarm system is not active. The LED will automatically return to green (along with the actual alarm system) when patient monitoring has resumed, or after exiting the message screen and going back to the patient monitoring screen.

The **'Reset Alarm'** hardkey is active only on patient monitoring screens when an alarm has been set off. In the event that an alarm occurs, pressing the **'Reset Alarm'** key will silence the audible alarm for the amount of time established by the Time Delay, if the audio alarm for the alarming parameter is enabled. The visual alarm indicator will not be reset; otherwise, the User might forget which parameter triggered the alarm system.

A visual alarm is indicated by a flashing parameter symbol on the screen. When an alarm condition arises, the BioZ.com® automatically displays the first patient monitoring screen in the viewing sequence that displays the alarming parameter. The order of display is as follows: Monitor then the Diagnostic Screen.

The alarms associated with the above parameters may be activated/de-activated at the User's discretion. The User also has the option to adjust the high and low set-points for generating the alarm condition(s), and the time delay associated with the '**Reset Alarm**' function.

1) To adjust the alarm conditions for HR, TFC and CI, press the '**Alarms**' softkey (Figure 57), the following screen will be displayed:

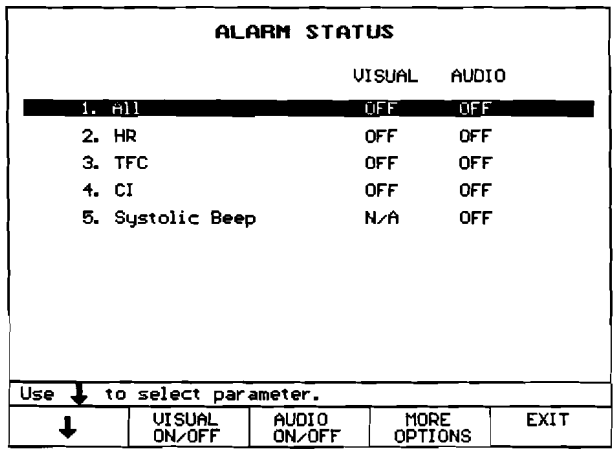


Figure 58. Alarm Status Screen

The User may activate/de-activate all or any combination of alarms for the parameters listed on the screen. Use the '↓' softkey to select the desired parameter, then press either the '**Visual (on/off)**' or '**Audio (on/off)**' softkeys to achieve the desired alarm configuration.

Note: It is not possible to activate an audio alarm without also activating the associated visual alarm for that given parameter.

2) Press the '**More Options**' softkey in order to adjust the **Volume**, **Limits** and alarm reset **Time Delay**.

3) To adjust the volume of the Audio Alarm, press the '**Volume**' softkey accordingly.

4) To set the high and low set-points for generating an alarm condition, press the **'Limits'** softkey. The following screen will be displayed:

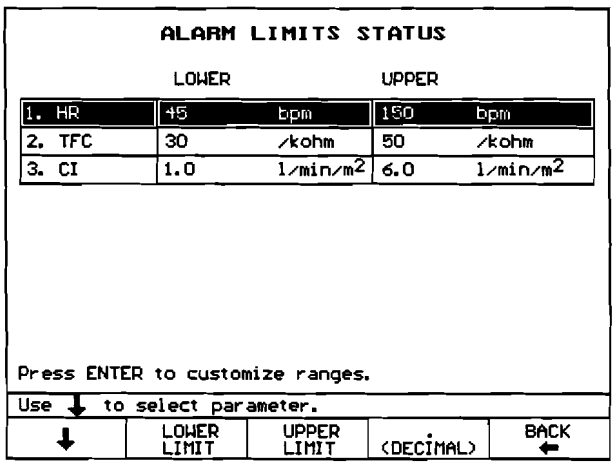


Figure 59. Alarm Limit Set-Point Screen

Use the '↓' softkey to select the desired parameter. To enter the desired high or low alarm limit, press either the **'Lower Limit'** or **'Upper Limit'** softkeys in order to place the cursor in the desired field. Press the numerical hardkeys and decimal point softkey to enter the desired value. If a value is entered incorrectly, press the **'Clear'** hardkey to erase the value and re-enter the correct value. Press the **'Enter'** hardkey to move to the next parameter.

Note: If the lower limit is greater than the upper limit, the cursor will not advance to the next parameter and will be placed in the lower limit box.

5) Press the **'Back←'** softkey to return to the previous screen.

The BioZ.com® allows the User to select the duration for the audible alarm to remain silent after the Reset Alarm function has been activated.

Note: Only the audible alarm is cleared, the visual alarm indicator will remain active while the alarm condition exists. This feature is necessary so that the parameter that generated the alarm will be identifiable to the User.

6) Press the **'Time Delay'** softkey, the following screen will be displayed:

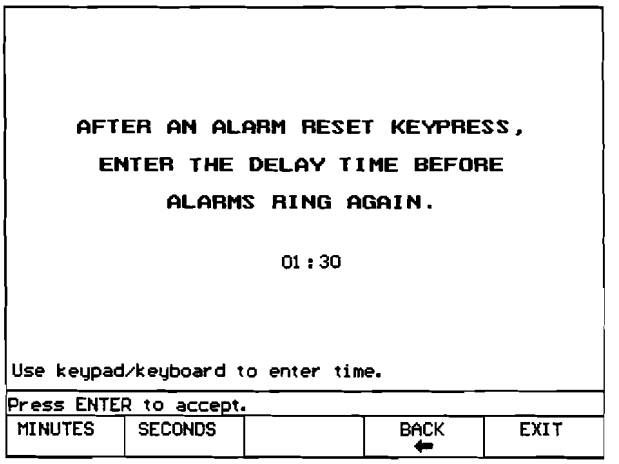


Figure 60. Alarm Reset Time Delay Screen

Press the **'Minutes'** and **'Seconds'** softkeys to place the cursor in the respective field. Press the numerical hardkeys to enter in the desired value. Press the **'Enter'** hardkey to lock in the value and place the cursor in the opposite field. If an incorrect value is entered, press the **'Clear'** hardkey to erase the selected field and re-enter the correct value.

The User can press the **'Exit'** softkey to return to the BioZ.com® Set-Up Menu screen.

8.1.1.2 Normal Ranges

The BioZ.com® Diagnostic Screen can display up to four of the calculated hemodynamic parameters at one time (listed below) in a horizontal bar graph format with vertical lines defining the Low, Normal, and High Ranges for the respective parameters. Though these ranges are defined at the factory, the User has the ability to specify the upper and lower limits of the Normal Range for each of the following parameters. In order to access this feature however, a password is required (see section 8.1.1.5 for instructions on how to set a personal password or use the default password, **1111**).

For adults, the "normal" range of cardiac output (CO) is between 4.5 – 8.5 l/min, depending on age, overall body size and composition. In the normal, resting state, the larger the body, the greater the cardiac output. Therefore, the more clinically useful parameter for defining normal cardiac function is the cardiac index (CI) and stroke index (SI). The BioZ.com® defines the limits for the normal range of CO and Stroke Volume (SV) as the product of the patient's Body Surface Area (BSA) and the limits for Cardiac Index (CI) and Stroke Index (SI) respectively. For example, if the patient's BSA was 2.0 m^2, and the lower limit for CI was 2.5 l min^{-1} m^{-2}, then the lower limit for CO would be:

$$2.0 \times 2.5 = 5.0 \text{ l/min}$$

Note: The normal ranges defined in the BioZ.com® are derived from the mean CI, HR, and MAP ± 2 SD, as published by Milnor, William R., M.D. *Hemodynamics.* (1982). Baltimore: Williams & Wilkins. Therefore, values lying within the normal range are not necessarily indicative of the optimal hemodynamic state for a given patient. Patients must be assessed based on their individual physiologic state.

- Cardiac Index – CI 2.5 – 4.7 l min^{-1} m^{-2}
- Stroke Index – SI 35 – 65 ml m^{-2}
- Systemic Vascular Resistance – SVR 742 – 1378 dyn sec cm^{-5}
- Systemic Vascular Resistance Index – SVRI 1337 – 2483 dyn sec cm^{-5} m^2
- Heart Rate – HR 58 – 86 beats min^{-1}
- Mean Arterial Pressure – MAP 84 – 100 mmHg
- Thoracic Fluid Content – TFC males: 30 – 50 $kohm^{-1}$, females: 21 – 37 $kohm^{-1}$
- Velocity Index – VI 33 – 65 1000^{-1} sec^{-1}
- Acceleration Index – ACI males: 70 – 150 100^{-1} sec^{-2}, females: 90 – 170 100^{-1} sec^{-2}
- Left Cardiac Work – LCW 5.4 – 10 kg m
- Left Cardiac Work Index – LCWI 3.0 – 5.5 kg m m^{-2}
- Systolic Time Ratio – STR 0.3 – 0.5

1) Press the **'Normal Ranges'** softkey, the following screen will be displayed:

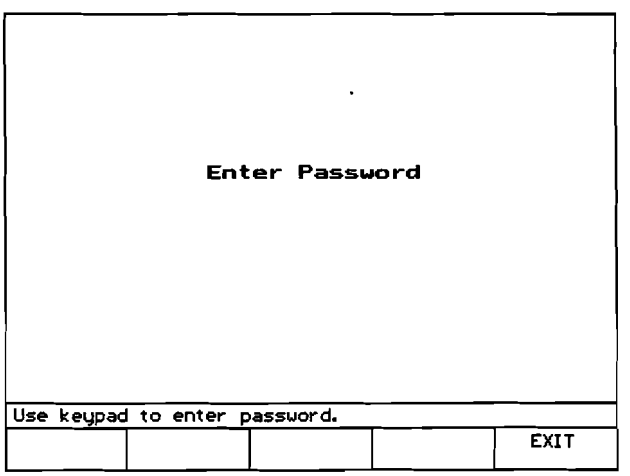


Figure 61. Password Entry Screen

2) Enter the four (4) digit password (see section 8.1.1.5 for instructions on how to set a personal password or use the default password, **1111**). If the password is correct, the following screen will be displayed, otherwise the User will be prompted to re-enter the correct password.

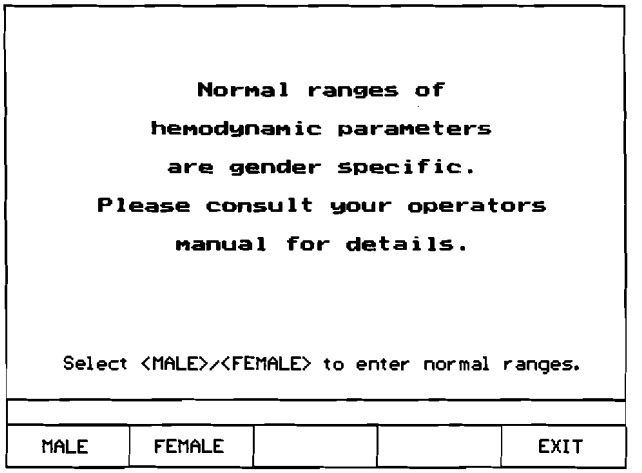


Figure 62. Normal Range Gender Screen

3) Press the appropriate "gender" softkey. The appropriate gender specific screen will be displayed:

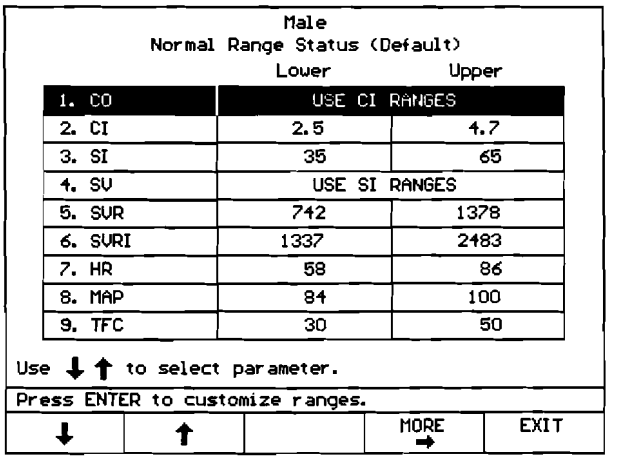


Figure 63. Normal Range Menu Screen (1)

4) To select the desired parameter, press the '↓' / '↑' softkeys or the appropriate numerical hardkeys. To select additional parameters, press the **'More→'** softkey. After the desired parameter has been highlighted, press the **'Enter'** hardkey. The "Softkey" selection at the bottom of the screen will be replaced with the following:

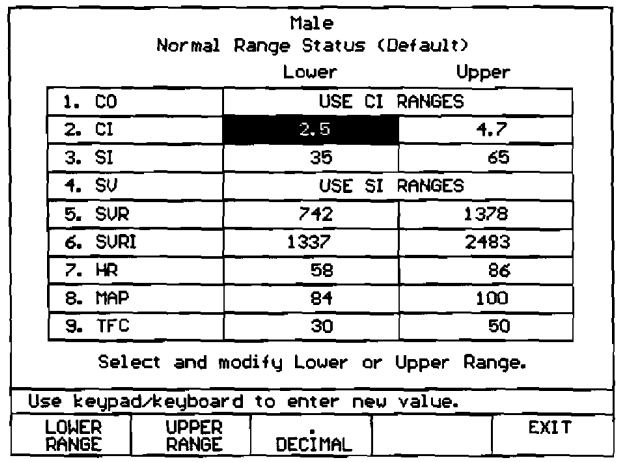


Figure 64. Normal Range Menu Screen (2)

5) Press the **'Upper Range'** and/or **'Lower Range'** softkeys to place the cursor in the respective cell. Use the numerical hardkeys and the **'Decimal'** softkey to enter the desired value. Press the **'Enter'** hardkey. If the Lower Range value is less than the Upper Range value, then the "Softkey" selection at the bottom of the screen will be returned to that of Figure 63. If this condition is not met, then the cursor will return to the Lower Range cell and the correct value should be re-entered.

6) Press the **'Exit'** softkey twice to return to the BioZ.com® Set-Up Menu Screen.

8.1.1.3 System Defaults

In order for the BioZ.com® to begin a patient monitoring session, certain information regarding the patient is required. This information is entered at the Patient Data Entry Screen. The BioZ.com® provides the User with the ability to define the default values and/or format/units of the necessary data entry fields.

1) To change the default settings for the Patient Data Entry Screen, press the **'System Defaults'** softkey (Figure 57). The following screen will be displayed:

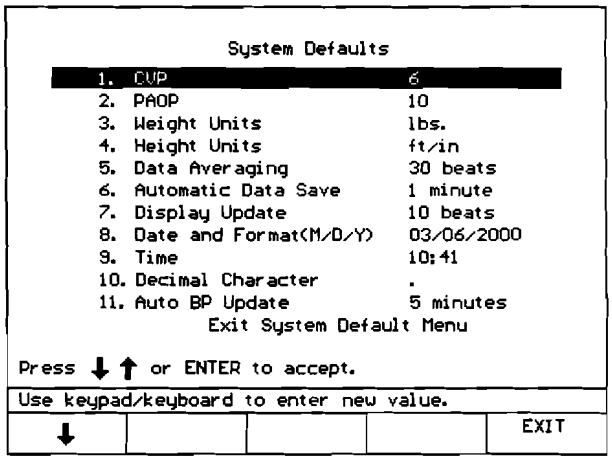

System Defaults
1. CVP 6
2. PAOP 10
3. Weight Units lbs.
4. Height Units ft/in
5. Data Averaging 30 beats
6. Automatic Data Save 1 minute
7. Display Update 10 beats
8. Date and Format(M/D/Y) 03/06/2000
9. Time 10:41
10. Decimal Character .
11. Auto BP Update 5 minutes
Exit System Default Menu
Press ↓ ↑ or ENTER to accept.
Use keypad/keyboard to enter new value.
↓
EXIT

Figure 65. System Default Menu Screen

The above screen displays the default settings for the values and/or format/units of the patient data fields.

2) System Default Entries:

- **CVP:** Central Venous Pressure is used in calculating the Systemic Vascular Resistance and its index (SVR and SVRI respectively).
- **PAOP:** Pulmonary Artery Occlusion Pressure is used in calculating the Left Cardiac Work and its index (LCW and LCWI respectively).
- **Weight Units:** Pounds (lbs.) or Kilograms (kgs.). The User may configure their device to accept weight values in either the standard or metric systems.
- **Height Units:** Feet and Inches (ft. and in.) or Centimeters (cm). The User may configure their device to accept weight values in either the standard or metric systems.
- **Data Averaging:** The data averaging determines the number of acceptable beats that are used to calculate the patient's hemodynamic values displayed on the screen. This value may be set between 1 and 60 beats.
- **Automatic Data Save:** The Automatic Data Save determines the frequency at which the hemodynamic values displayed on the screen are saved to the patient's file. This value may be set to a value between 1 second and 999 minutes, or can be set to the display update frequency.. For example, if the Automatic Data Save is set to 5 minutes a 'data set' will be saved to the patient's file every 5 minutes. If it is set to the display update frequency, a new data set will be

saved to the patient's file every time the display updates (every 1 to 99 beats, depending on Display Update configuration).

- **Display Update:** The Display Update determines the frequency at which the hemodynamic values are refreshed (updated) on the screen. The Display Update may be configured between 1 and 99 beats. For example, if the Display Update is set to 10 beats the screen will be refreshed every 10 acceptable beats that the device detects.
- **Date and Format:** The Date and Format can be selected as either MM/DD/YYYY or DD/MM/YYYY. The User must enter in two digit values for the month and the day and four digit values for the year.
- **Time:** The Time must be entered in 24 hour format.
- **Decimal Character:** The Decimal Character can be configured as a period (.), or a comma (,).
- **Auto BP Update:** The Auto BP Update determines the frequency at which the device will automatically take a new blood pressure measurement. This may be configured between 1 and 99 minutes.

3) To accept the factory default setting for a particular field, and move to another field, press the '↓' softkey or the **'Enter'** hardkey to highlight the desired field.

4) To change the default setting of a field that contains a numerical value (i.e., the CVP, PAOP, Data Averaging, Automatic Data Save, Display Update and Time) perform the following:

- Select the desired field.
- Press the **'Clear'** hardkey.
- Press the appropriate numerical hardkeys to enter the desired value.
- Press either the '↓' softkey or **'Enter'** hardkey to accept the entry and advance to the next field.

Note: If a default value is cleared, and the '↓' softkey or **'Enter'** hardkeys are pressed prior to entering a value in the field, the default value will be restored and the highlight bar advanced to the next field.

5) To change the unit of entry/display for the Height and/or Weight fields, perform the following:

- Select the desired field.
- Press the appropriate softkey for the desired unit of entry/display.

Note: the highlight bar is automatically advanced after selecting the desired unit of entry.

6) To change the format for the date, and/or decimal character fields, perform the following:

- Select the desired field.
- Use the appropriate softkeys at the bottom of the screen to select the desired format and/or decimal character.

7) After the desired system default settings have been entered, select "Exit System Default Menu" and press either the **'Enter'** hardkey or the **'Exit'** softkey. The User will be returned to the BioZ.com® Set-Up Menu (Figure 57).

8.1.1.4 Defining Event Labels

The BioZ.com® allows the User to define desired Events in the course of a patient's monitoring session. In order to define the list of desired event labels perform the following:

1) From the System Set-Up screen (Figure 57) press the **'More→'** softkey. The following screen will be displayed:

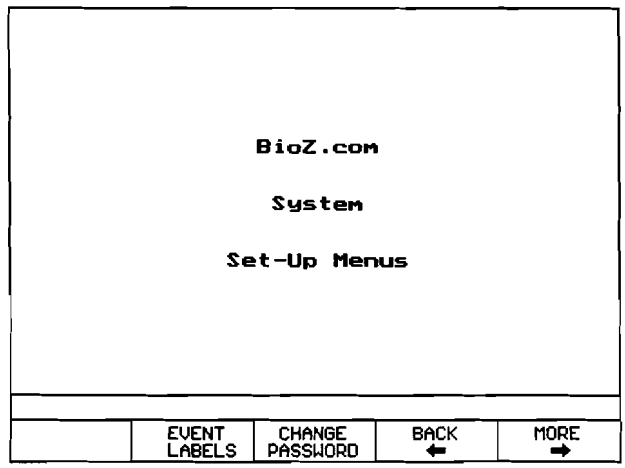


Figure 66. BioZ.com® System Set-Up Menu (Screen 2)

2) Press the 'Event Labels' softkey. The Events List screen will be displayed:

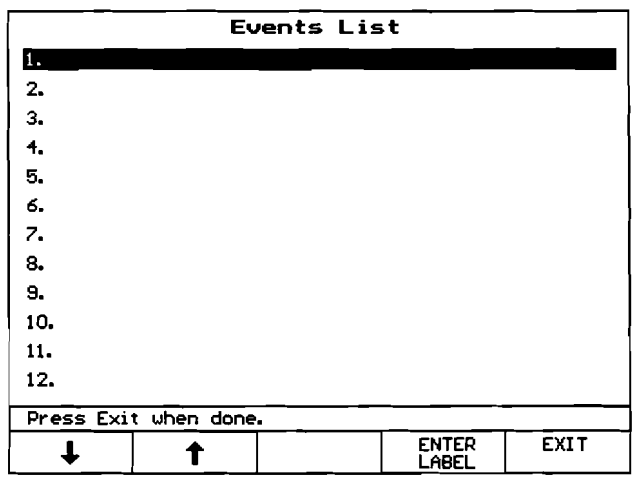


Figure 67. Events List Screen

3) Press the 'Enter Label' softkey. Type in the desired label using the keyboard or the Text Entry screen on the BioZ.com®. Each Event label is restricted to 50 characters.

4) Press <Enter> from the external keyboard or the 'Enter' hardkey on the BioZ.com® front panel to accept the label.

5) From the Events List, press the 'Exit' softkey when finished adding event labels.

8.1.1.5 Change Password

The BioZ.com® requires a four (4) digit numerical password in order to customize the System default settings/configurations and/or screen configurations. The default password is **1111**. The User is advised to set his or her own personal password.

Note: If you forget your password, contact the Technical Service Department at (800) 778-4825-Option 3 (USA) or (858) 535-0202 (outside USA) Option 3.

Press the **'Menu'** hardkey to access the BioZ.com® Set-Up Menu Screen, press the **'More→'** softkey and perform the following:

1) To set the password, press the **'Change Password'** key. The following screen will be displayed.

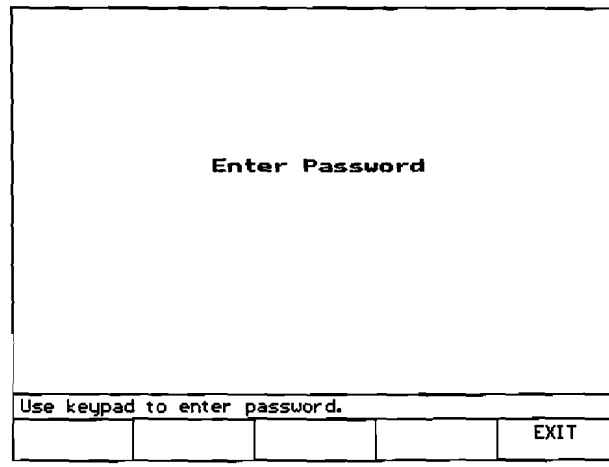


Figure 68. Password Entry Screen

2) Key in the factory default password, '1111' (or the current password). After the fourth number has been entered, the following screen will be displayed:

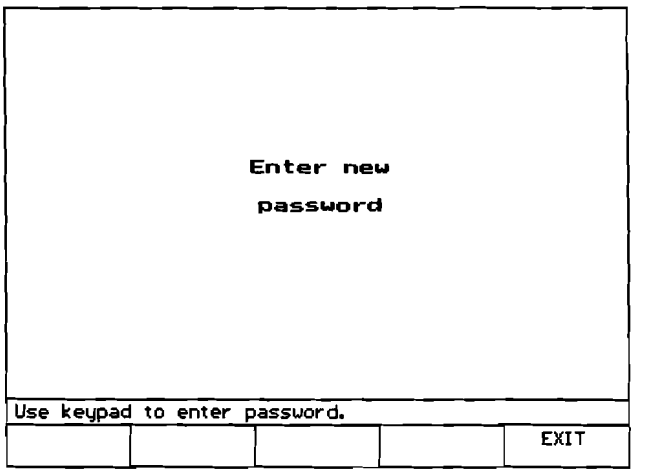


Figure 69. New Password Entry Screen

3) Key in the desired four (4) digit numerical password. After the fourth digit has been entered, the following screen will be displayed:

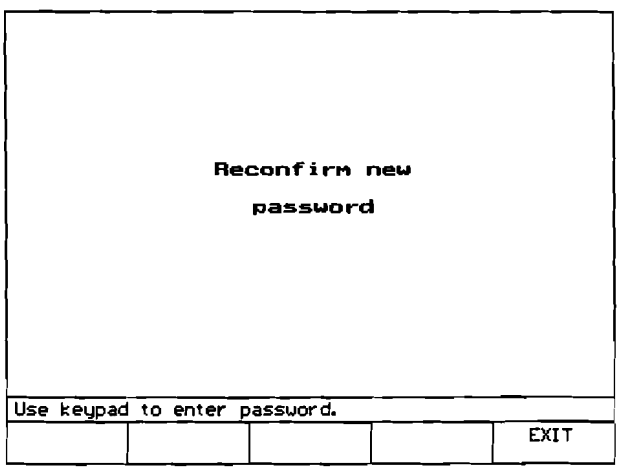


Figure 70. New Password Re-Confirmation Entry Screen

4) Confirm the new password by re-entering the new four-digit password. If entered correctly the following screen will be displayed:

Figure 71. New Password Verification Screen

5) Press the **'Exit'** softkey to return to the BioZ.com® Set-Up Menu (Figure 57).

6) Press the **'More→'** softkey, the following screen will be displayed:

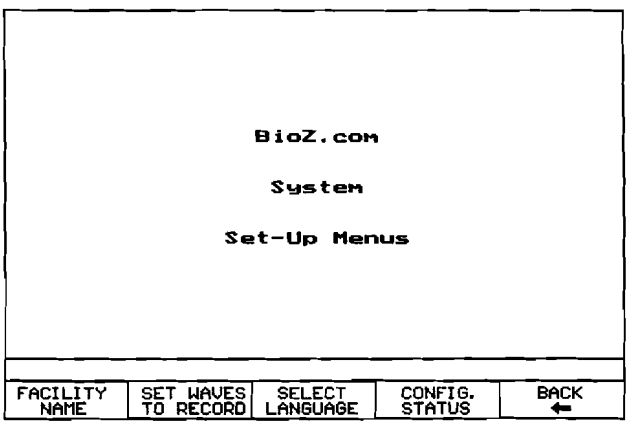


Figure 72. System Set-Up Menu

Note: The **'Config. Status'** feature is not available on all models or software versions.

8.1.1.6 Facility Name

For the purpose of printing reports, the BioZ.com® can store the name and address of the User/facility. To enter the Facility information, perform the following:

1) Press the **'Facility Name'** softkey, the following screen will be displayed:

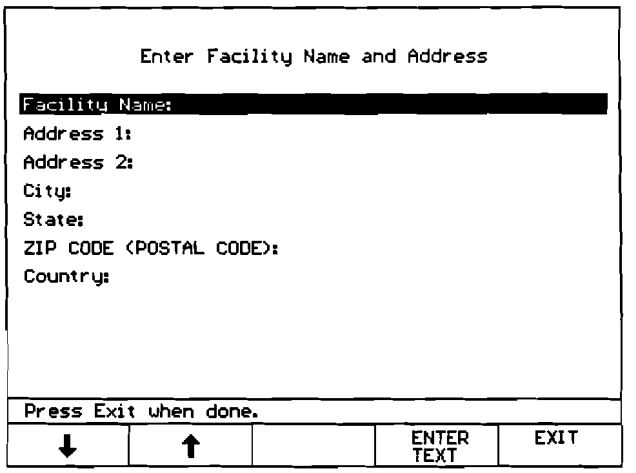


Figure 73. Facility Name Entry Screen

Use the '↓' and/or '↑' softkeys to select desired field.

2) Press the **'Enter Text'** softkey to access the Text Entry Screen and follow the steps displayed on the screen.

Note: You must press the **'Enter Text'** softkey to enter numerical data also.

3) Press the **'Enter'** softkey to select the next field listed on the Facility Name Entry Screen.

4) After all entries have been completed, press the **'Exit'** softkey to return to the BioZ.com® Set-Up Menu.

8.1.1.7 Waveform Recording Options

- During a patient monitoring session (or Demo Mode operation), the BioZ.com® will automatically store patient data at a predetermined interval (see section 8.1.1.2). In addition, the User can press the **'Save Waveform'** softkey to save the previous 26 seconds of waveform to the patient's record.

Note: The Save Waveform function is a diagnostic troubleshooting tool. Saved waveforms may only be viewed by CardioDynamics' Technical Support Engineers. The User does not have access to this data.

8.1.1.8 Select Language

The BioZ.com® operational software has multi-language capability. The User may choose any of the following languages:

- English
- French
- Spanish

- Italian
- German
- Danish
- Dutch

To select the desired language, perform the following steps:

At the BioZ.com® Set-Up Menu, press the **'Select Language'** softkey. The following screen will be displayed.

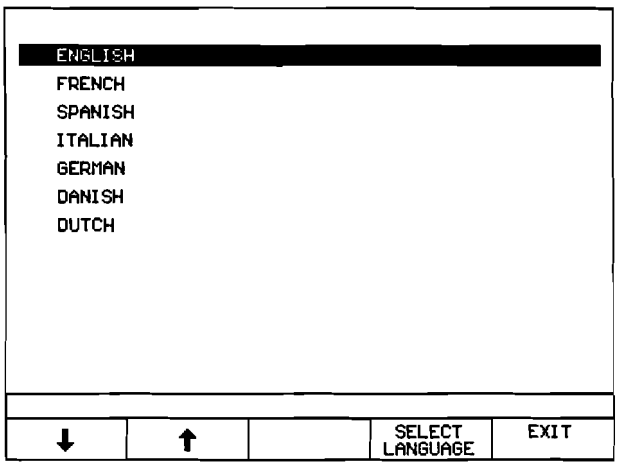


Figure 74. Language Selection Screen

1) Press the '↓' and/or '↑' softkeys to select the desired language.

2) Press the **'Select Language'** softkey to lock in the desired language and return to the BioZ.com® System Menu Screen.

8.1.1.9 Configure Status Report

Note: The ability to configure a Custom Status Report is not available on all models and software versions.

The BioZ.com® has the ability to configure the Hemodynamic Status Report so that only the desired parameters are displayed. To configure the Hemodynamic Status Report, perform the following steps:

1) At the BioZ.com® Set-Up Menu, press the **'Config. Status'** softkey. The following screen will be displayed:

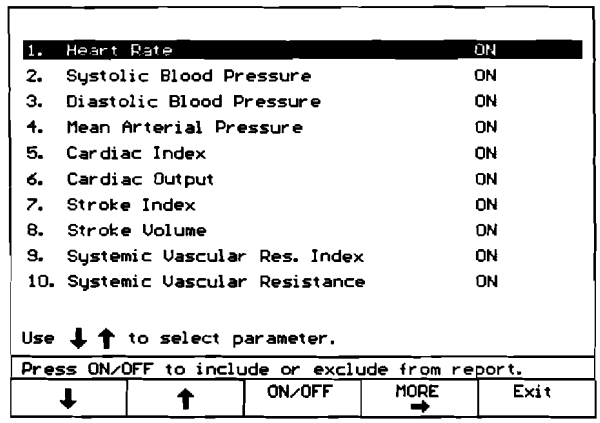


Figure 75. Custom Status Report Selection Screen (1)

2) Press the '↓' and/or '↑' softkeys to highlight the desired parameters and press the **'ON/OFF'** softkey to select the desired parameters to display on the Custom Status Report.

3) Press the **'More→'** softkey, the following screen will be displayed:

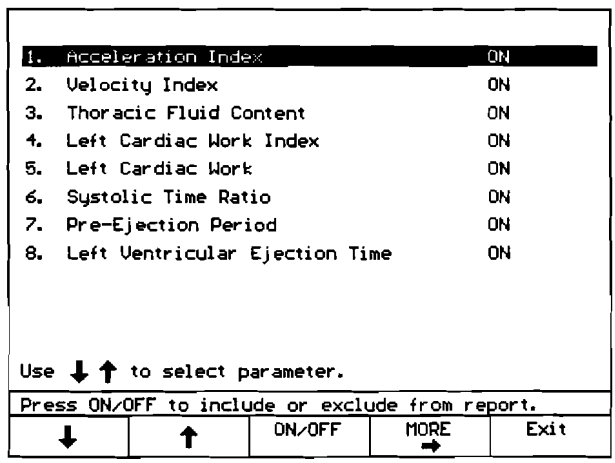


Figure 76. Custom Status Report Selection Screen (2)

4) Press the '↓' and/or '↑' softkeys to highlight the desired parameters and press the **'ON/OFF'** softkey to select the desired parameters to display on the Custom Status Report.

5) When finished selecting the desired parameters, press the **'Exit'** softkey to return to the BioZ.com System Set-Up Menus screen (Figure 72).

8.1.2 Configure Screens

There are five basic patient monitoring screens.

- Monitoring Screen
- Diagnostic Screen

- Therapeutic Screen
- Trend Screen
- Waveform Screen

All but the Therapeutic screen may be configured to display the various hemodynamic parameters provided by the BioZ.com®.

8.1.2.1 Monitoring Screen

When a monitoring session begins, the first screen displayed by the BioZ.com® is the patient Monitoring Screen. The Monitoring Screen consists of a combination of up to five (5) data display cells and two (2) graphics display cells. Each data display cell will provide the value for one of the hemodynamic parameters provided by the BioZ.com®. The User has the option to configure these cells to their specific requirements. The graphic display cells are used to display the ECG and Impedance waveforms (or whatever the User has configured for the Waveform Screen).

The screen configuration menu on the BioZ.com® is password protected. Key in the password that was set in section 8.1.1.5 or enter in the default password, **'1111'**. When the password is entered correctly, the BioZ.com® Screen Configuration Menu will be displayed.

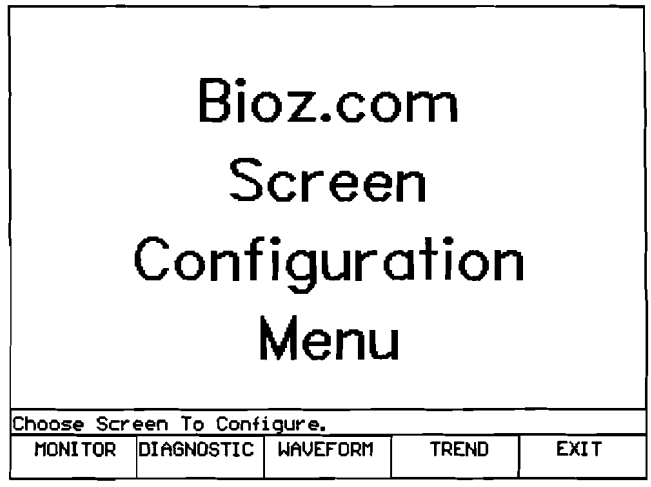


Figure 77. BioZ.com® Screen Configuration Menu Screen

1) Press the **'Monitor'** softkey. The following screen will be displayed:

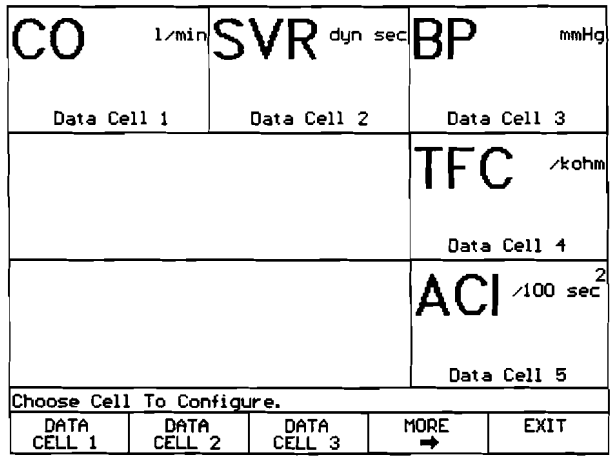


Figure 78. Patient Monitoring Screen Cell Configuration Menu (1)

Note: Figure 78 may not reflect the configuration of the Data/Graphic Display Cells for your device.

The User has the ability to choose which hemodynamic parameters will be displayed and which cells will display them. Follow the general steps outlined below to configure the Monitoring Screen.

- Press the appropriate softkey to select the desired data cell to configure.
- Use the '↓' and/or '↑' softkeys to select the desired hemodynamic parameter to display in the cell, or select **'off'** to deactivate the cell.
- Press the **'Accept'** softkey, or the **'Enter'** hardkey, to set the cell configuration.
- Repeat the above steps for each individual cell.

Note: When data display cells D-4 and D-5 are both deactivated, both of the Graphic Cells will "elongate" so as to fill the vacated screen area.

See section 6.3 for a sample Monitoring Screen configuration change.

2) When finished configuring the Monitoring Screen, press the **'Exit'** softkey to return to the BioZ.com® Screen Configuration Menu.

8.1.2.2 Diagnostic Screen

The Diagnostic screen displays up to four of the hemodynamic parameters in a horizontal bar graph format. Low, normal, and high ranges are defined along each bar so as to aid the User in quickly identifying the hemodynamic condition of the patient.

As with the patient Monitoring Screen, the User may configure the Diagnostic screen to display the hemodynamic parameters of their choice. Follow the general steps outlined below to configure the Diagnostic Screen.

At the BioZ.com® Screen Configuration Menu, press the **'Diagnostic'** softkey. The following screen will be displayed:

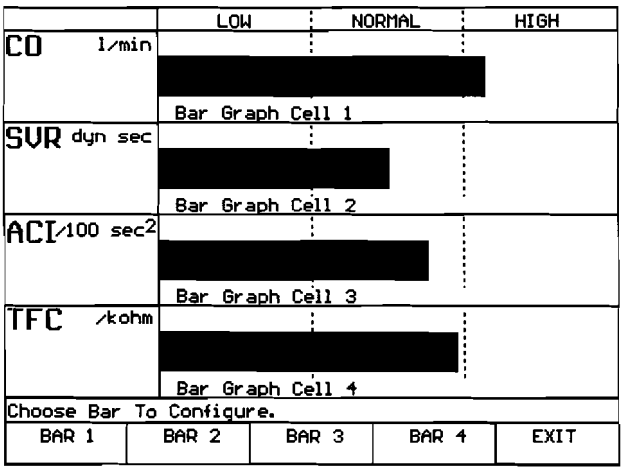


Figure 79. Patient Diagnostic Screen Cell Configuration Menu (1)

Note: Figure 79 may not reflect the configuration of the Bar Graphs for your device.

- Press the appropriate softkey for the desired "bar graph" to configure, the following screen will be displayed:

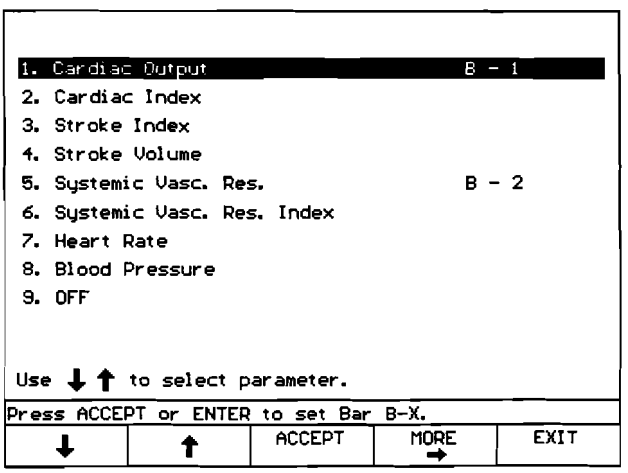


Figure 80. Hemodynamic Parameter Set-Up Menu (1)

- Use the **'More→'** softkey along with the '↓' and/or '↑' softkeys to select the parameter to assign to the bar graph.
- Press either the **'Accept'** softkey or the **'Enter'** hardkey to effect the change.
- Repeat the above three steps to set the other bar graphs.
- Press the **'Exit'** softkey to return to the BioZ.com® Screen Configuration Menu.

8.1.2.3 Trend Screen

The Trend Screen will display trending plots for two of the hemodynamic parameters at a given time as well as the current value for the parameter. The User can define two combinations of two parameters for the Trend Screen to display.

To set the default Trend Screen parameters, perform the following steps:

1) At the BioZ.com® Screen Configuration Menu, press the **'Trend'** softkey. The following screen will be displayed:

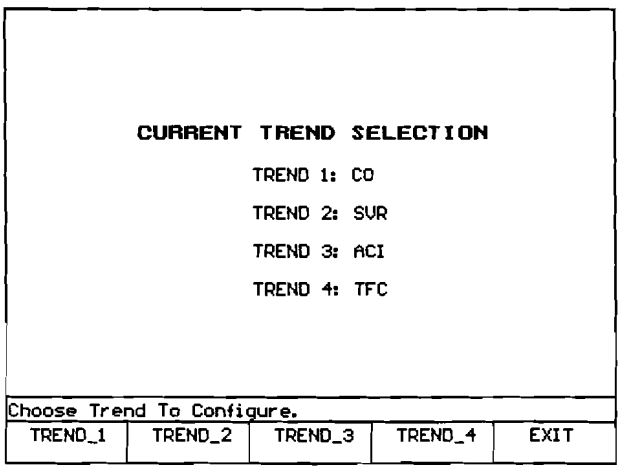


Figure 81. Trend Screen Cell Configuration Menu Screen

The two default settings for the Trend Screen consist of either Trends 1 and 2 or Trends 3 and 4.

- Press the appropriate softkey for the desired trend.
- Use the **'More→'** softkey along with the '↓' and/or '↑' softkeys to select the parameter to assign to the selected trending plot.
- Press either the **'Accept'** softkey or the **'Enter'** hardkey to effect the change.
- Repeat the above three steps to set the other trending plots.
- Press the **'Exit'** softkey to return to the BioZ.com® Screen Configuration Menu.

8.1.2.4 Waveform Screen

The Waveform Screen is similar to the Monitoring Screen. There are two (2) graphics cells for displaying up to two (2) of the five (5) waveforms provided by the BioZ.com® as well as five (5) data display cells. The data display cells are the same as those displayed on the Monitoring Screen. The advantage of this screen is that the User can cycle between all five (5) waveforms, while the monitoring screen only lets the User view the two default (ECG and Impedance) waveforms.

To set the two initial default waveforms to display in the Waveform Screen, perform the following:

At the BioZ.com® Screen Configuration Menu, press the **'Waveform'** softkey. The following screen will be displayed:

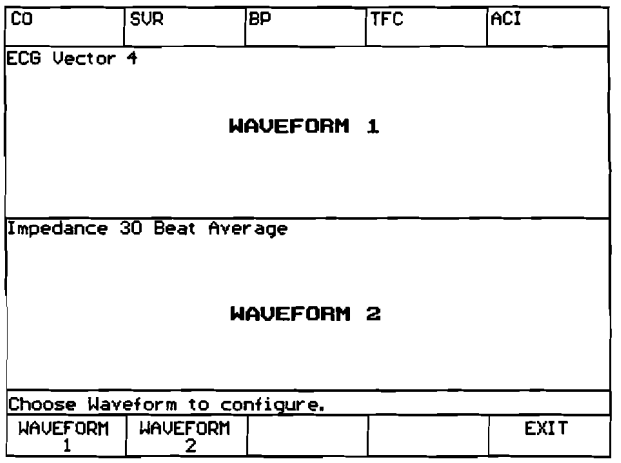


Figure 82. Waveform Screen Cell Configuration Menu Screen

- Press the appropriate softkey to configure the desired waveform cell

  The following waveforms are available to choose from:

  - Impedance Waveform (Delta Z)
  - ECG Waveform (any of four vectors)
  - dZ/dt Waveform (first derivative of Delta Z)
  - Pacer Impulse Waveform

    For patients with pacemakers, the BioZ.com® can detect when the pacemaker triggers and then display that trigger as a series of corresponding impulses.

  - Spike Enhancement Waveform

    The spike enhancement waveform is an ECG waveform that also displays a 'spike' for each pacemaker trigger signal.

- Use the '↓' and/or '↑' softkeys to select the parameter to assign to the selected Waveform cell.
- Press either the **'Accept'** softkey or the **'Enter'** hardkey to effect the change.
- Repeat the above steps to set the remaining waveform cell.
- Press the **'Exit'** softkey to return to the BioZ.com® Screen Configuration Menu.

8.1.3 Update Patient Information

The BioZ.com® provides the User with a convenient method for updating information regarding a patient. This feature is available to allow the User to view the patient's information and make only necessary changes without having to re-enter the patient's entire profile. For example, if the patient's weight needed to be amended or the method for monitoring blood pressure was changed, the **'Update Patient Information'** function would provide access to effect these changes without having to stop monitoring and re-enter the entire patient information into the system.

At the BioZ.com® User Menu, press the **'Update Patient Information'** softkey, the following screen will be displayed:

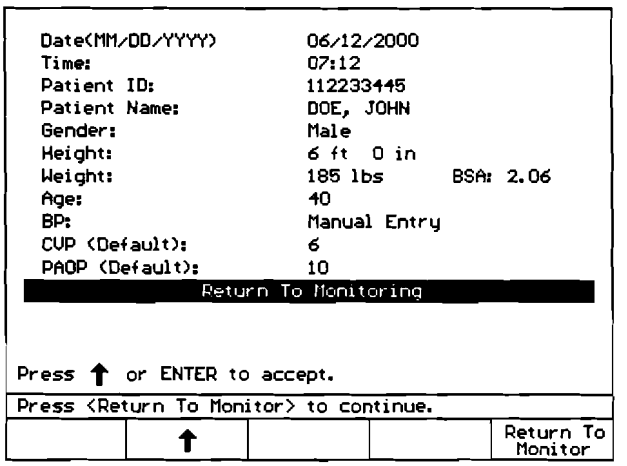


Figure 83. Patient Data Entry Confirmation Screen

- Use the '↓' and/or '↑' softkeys to highlight the desired field(s).
- Press the **'Clear'** hardkey to erase the current information.
- Enter the amended value and/or text.
- Press the **'Enter'** hardkey to effect the change to the selected field and advance to the next field.

Note: If the **'Enter'** hardkey is pressed while the field is cleared, the field will revert to the default setting.

- After changes have been made, press the **'Return to Monitor'** softkey, the following screen will be displayed:

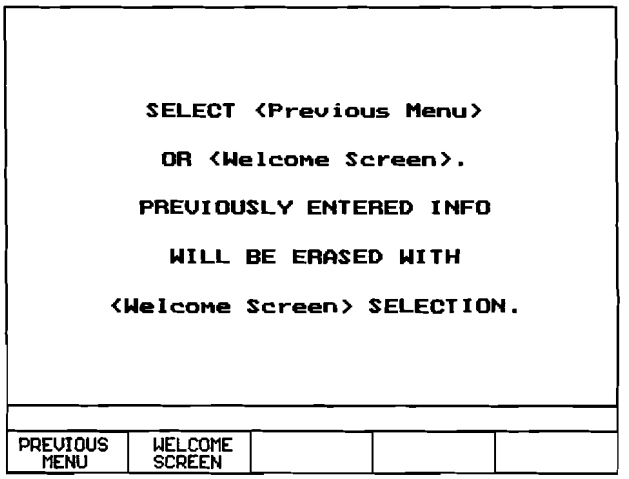


Figure 84. Patient Data Entry Exit Screen

- Press the **'Previous Menu'** softkey to return to the BioZ.com® User Menu Screen.

8.2 Patient Records Management

The BioZ.com® allows the User to add a new patient, add new data to a previous patient's record, and review or delete the stored patient records.

8.2.1 Adding a New Patient

From the Welcome Screen (Figure 55), press the **'Start Monitor'** softkey. Enter the patient's information into the Patient Data Entry screen. When complete, press the **'Start Monitor'** softkey.

8.2.2 Add New Data to Previous Patient Record

From the Welcome Screen, press the **'Start Monitor'** softkey. From the Patient Data Entry screen, press the **'Stored Pt. Info'** softkey. When the desired patient is found, press either the **'New File'** softkey or the **'Add to File'** softkey. Either choice will bring up the Patient Data Entry Screen with the patient's data filled in. Make changes by pressing the **'Make Changes'** softkey, or press the **'Start Monitor'** softkey to start monitoring.

Note: If **'Manual Entry'** is the method of blood pressure, the User must enter a new blood pressure value before beginning the monitoring session.

8.2.3 Review or Delete Patient Records

To review a patient record, press the **'Review Records'** softkey from the Welcome Screen.

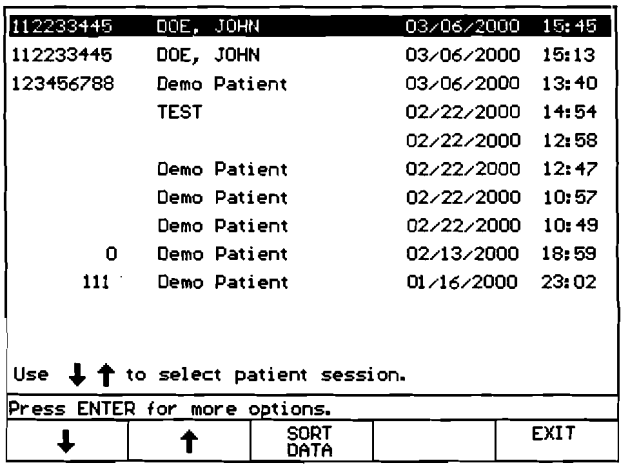


Figure 85. Patient Record Review Screen (1)

Note: The above screen is for informational purposes only and does not represent the actual Patient files stored in the BioZ.com®.

1) Press the '↓' and/or '↑' softkeys accordingly to highlight the desired patient record and press the **'Enter'** hardkey. [If there are more than 10 patient files, the User may press the **'Next Screen'** or **'Previous Screen'** hardkeys to scroll down or up to the rest of the patient files.] The following screen will be displayed:

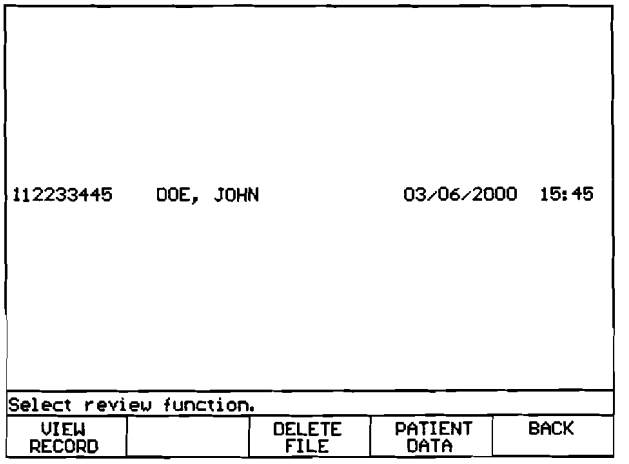


Figure 86. Patient Record Review Screen (2)

From the above screen, the User has the ability to view the patient record, delete the file, and/or view patient data. Press the **'View Record'** softkey. The following screen will be displayed:

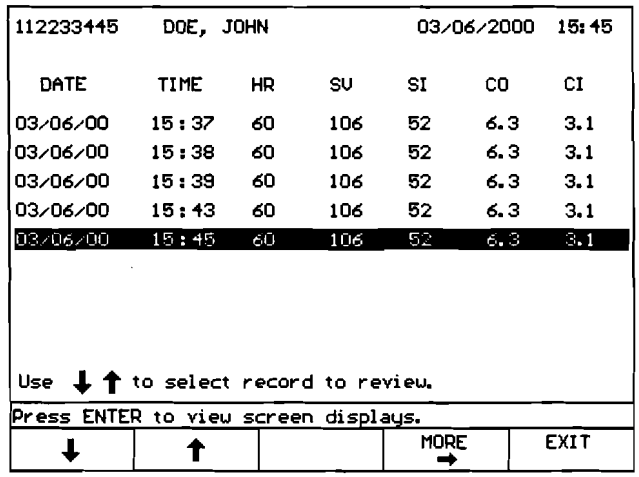


Figure 87. Patient Record Review Screen (3)

The above screen will display the numerical data for the parameters shown on the patient's last recorded monitoring screen. The first 1 to 5 hemodynamic parameters displayed will be those selected for that specific patient monitoring screen. The remaining parameters will be displayed on the following screens. To view the remaining hemodynamic parameters, the User may press the **'More→'** softkey. If there are more than 8 recordings in a patient data file, the User may press the '↑' softkey or the **'Previous Screen'** hardkey to scroll up to the rest of the patient record data sets. To access a record of an individual data set:

2) Press the **'Enter'** hardkey after selecting the desired data set. The following screen will be displayed.

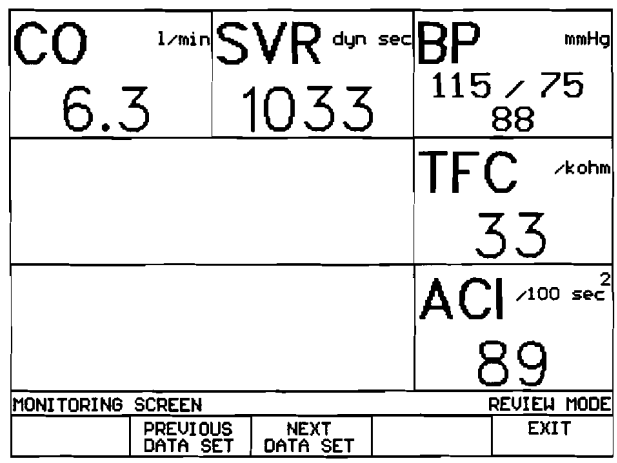


Figure 88. Patient Record Review Monitor Screen (4)

Note: "Review Mode" will be displayed in the lower right corner of the screen while in the Review Record function. Patient waveforms are not saved with each data set.

The BioZ.com® will display the patient Monitoring Screen in the appropriate screen configuration set by the User during that particular patient monitoring session.

3) Press the **'Next Screen'** or **'Previous Screen'** hardkeys to scroll through the patient monitoring screens.

4) Press the **'Next Data Set'** or **'Previous Data Set'** softkeys to access other recorded data sets for the selected patient.

5) Press the **'Exit'** softkey three (3) times to return to the patient Monitoring Screen.

8.3 Printing Information

The BioZ.com® provides the User with the ability to print pre-formatted reports. Printing functions are available to the User while both conducting a "live" or "demo" patient monitoring session and from the Record Review function.

The BioZ.com® is compatible with Printers utilizing the Hewlett Packard PCL3 (and more recent) communication protocol.

Ensure that a printer connection has been established through the printer port located on the rear panel of the BioZ.com® prior to pressing the **'Print'** hardkey.

Caution! When monitoring patients with indwelling catheters, the printer must be used with a Hospital/Medical grade power supply. Should you have questions or require clarification, please contact CardioDynamics Technical Service for more information.

8.3.1 Print Screen Report

The Print Screen Report (Appendix B. PRINT SCREEN REPORT) consists of the following:

- Patient Demographics
- Facility Information
- An image of a patient monitoring screen
- To print a report that contains an image of the screen that the User is currently viewing, press the **'Print'** hardkey followed by the **'Print Screen'** softkey. The Print Screen Report will be printed and the softkeys will return to those of the screen of entry.

  Note: If the printer is not connected, or unrecognizable to the BioZ.com®, an error message will be displayed.

8.3.2 Hemodynamic Summary Report

The Hemodynamic Summary Report (Appendix C. HEMODYNAMIC SUMMARY REPORT) generates a report that lists each recorded data set of the patient currently being monitored, or of previously monitored patients.

The Hemodynamic Summary Report consists of the following:

- Facility information
- Patient demographics
- Values for the five hemodynamic parameters displayed on the patient Monitoring Screen
- Event Labels

To print the Hemodynamic Summary Report, perform the following:

- Either press the **'Print'** hardkey while currently monitoring a patient, or select a previously recorded patient record (see section 8.2) and then press the **'Print'** hardkey.

The Print Command softkeys will be displayed (Figure 27).

- Press the **'Summary Report'** softkey. Select the duration of the report from the available options (**Last 8 hours**, **Last 12 hours** or **Last 24 hours**), or select **Custom Start/End**. If the User selects the **Custom Start/End** softkey, the User will be directed to use the '↓' and/or '↑' softkeys to select the **Start of Report** and then the **End of Report.** The User then presses the **Enter** hardkey, and the Hemodynamic Summary Report will be printed.

8.3.3 Hemodynamic Trend Report

The Hemodynamic Trend Report (Appendix D. HEMODYNAMIC TREND REPORT) graphically displays trending data for the five parameters displayed on the patient Monitoring Screen, and includes the following information:

- Facility information
- Patient demographics
- Event labels
- Percent of recorded data sets within the normal range

To print the Hemodynamic Trend Report, perform the following steps:

- Either press the **'Print'** hardkey while currently monitoring a patient, or select a previously recorded patient record (see section 8.2) and then press the **'Print'** hardkey.
- Press the **'Trend Report'** softkey. Select the duration of the report from the available options (**Last 8 hours**, **Last 12 hours** or **Last 24 hours**), or select **Custom Start/End**. If the User selects the **Custom Start/End** softkey, the User will be directed to use the '↓' and/or '↑' softkeys to select the **Start of Report** and then the **End of Report.** The User then presses the **Enter** hardkey to print the Hemodynamic Trend Report.

8.3.4 Hemodynamic Status Report

The Hemodynamic Status Report (Appendix E. HEMODYNAMIC STATUS REPORT) consists of the patient's 18 hemodynamic parameters for a specified moment in time, and can be configured to display the user's desired parameters. The Complete and Custom status reports include the following:

- Facility information
- Patient demographics

- Bar graphs of the 18 Hemodynamic Parameters (as per User Configuration) and their normal ranges

- The two waveforms displayed by the Waveform Screen (Live Mode only)

To print the Hemodynamic Status Report, perform the following steps:

- Press the **'Print'** hardkey while currently monitoring a patient, or select a previously recorded patient record (see section 8.2) and then press the **'Print'** hardkey.

- Press the **'Status Report'** softkey. Select either the **'Complete'** or the **'Custom'** softkey. If the User is monitoring in Live Mode, the Hemodynamic Status Report will print.

Note: Custom status reports must be configured prior to pressing the **'Print'** hardkey. See section 8.1.1.9 for details. The ability to configure a Custom Status Report is not available on all models and software versions.

- To print the report in Review Records mode, use the '↓' and/or '↑' softkeys to select the record, and press the **'Enter'** hardkey to print the Hemodynamic Status Report.

Note: Hemodynamic Status Reports printed in Review Records Mode will not have waveforms.

9 TROUBLESHOOTING

If you have any problems that you are unable to solve, contact CDIC's Technical Service Department at 800-778-4825 (option 3), or outside of the USA at 858-535-0202 (option 3), or by e-mail at tech-support@cardiodynamics.com. Emergency After Hours Technical Support is available, 7 days a week between the hours of 6 a.m. and 9 p.m., Pacific Time, by cell phone at 866-880-6674.

An optional Service Manual is available for purchase for non-warranty repairs.

9.1 Signal Acquisition Error

In the event that the BioZ.com® is unable to process an ECG and/or Impedance (delta Z) waveform for more than a 1-minute period, the following error message will be displayed:

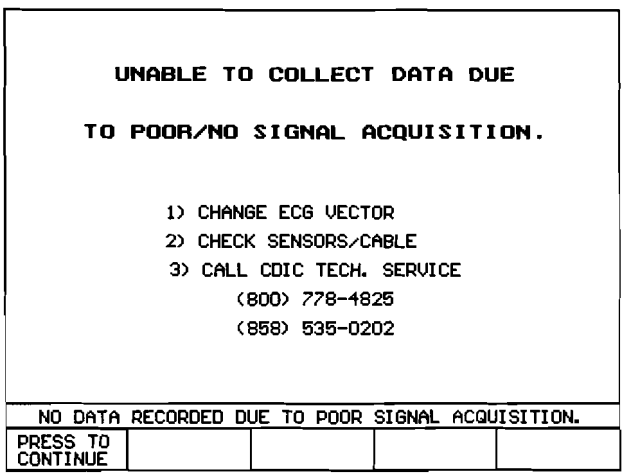

UNABLE TO COLLECT DATA DUE
TO POOR/NO SIGNAL ACQUISITION.
1) CHANGE ECG VECTOR
2) CHECK SENSORS/CABLE
3) CALL CDIC TECH. SERVICE
(800) 778-4825
(858) 535-0202
NO DATA RECORDED DUE TO POOR SIGNAL ACQUISITION.
PRESS TO CONTINUE

Figure 89. Poor ECG/Impedance Waveform Error Screen

The **'Press to Continue'** softkey will return the User to the screen of entry. The screen of entry will remain in a "frozen" state with the following message displayed until the condition has been remedied.

LAST GOOD DATA SET RECORDED AT HH:MM

- Change the ECG vector (ensure that the systolic beep is activated and listen for detection) and wait at least 30 seconds to allow the screen to update. Repeat for all four ECG vectors if necessary.

The User should follow the instructions displayed on the screen and ensure that:

- The sensors are in the correct positions.
- There is good contact between the patient's skin and the sensors.
- The patient cable is attached to the sensors in the proper location(s).
- The patient cable is connected to the BioZ.com®.

If the above steps don't eliminate the error, replace the sensors and resume monitoring the patient. Should the error condition persist, contact CDIC's Technical Service department at 800-778-4825 (USA) or 858-535-0202, Option 3.

9.2 Low Battery

If your BioZ.com® is equipped with an optional battery the following screen will be displayed when the battery is less than 20 percent of full capacity:

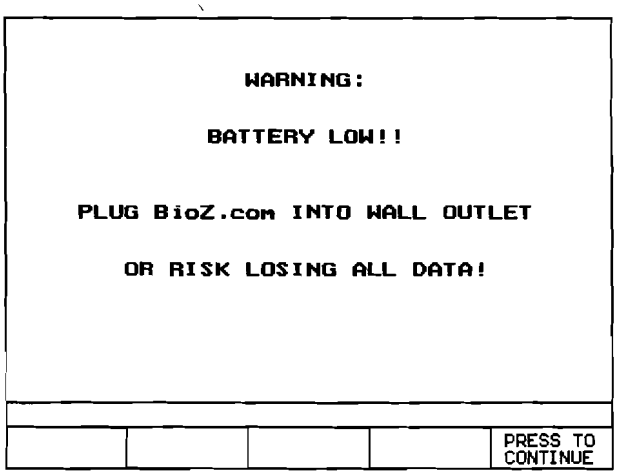


Figure 90. Low battery Warning Screen

Note: The Battery will re-charge automatically each time AC power is applied to the device whether or not the power switch is turned on. There are no special instructions that must be adhered to in order to safely operate and/or charge the battery.

The **'Press to Continue'** softkey returns the User to the screen of entry. This warning screen will be displayed every 60 seconds or until AC power is restored. If the above error screen is displayed, plug the BioZ.com® into the proper AC power source as soon as possible.

9.3 Printing Errors

Printer not detected

This could be due to either the printer not being connected/powered on prior to turning on the BioZ.com®, no ink in the cartridge, a bad printer cable, or a fault within the BioZ.com®. To determine the failure mode, perform the following steps:

- Check the printer ink cartridge.
- Check the printer for any paper jams.

- Turn off the BioZ.com® and the printer. Make sure the printer cable is attached to both the BioZ.com LPT port and to the printer.
- Turn on the printer.
- Turn on the BioZ.com®.
- Attempt to print the report. If the error message is still in effect, repeat the above steps while using a different printer cable.

Contact CardioDynamics' Technical Support department if the above steps fail to resolve the problem.

10 NOMINAL SPECIFICATIONS

The BioZ.com® has input protection against defibrillators and electro-surgical devices.

Component	Physical Specifications	Technical Information
Portable Intel™ based CPU with built-in flat screen EL monitor and integrated membrane keyboard	14.0 in x 12.1 in x 7.0 in (35.6 cm x 30.8 cm x 17.8 cm) 12.1 lbs. (5.5 kg) High Impact Plastic	Electrical isolation to UL 2601, IEC601 specifications
	4.0 mA rms (Max), 60 kHz (Min)	Measurement Current
Power Specification	100-240V, 0.5-1.5 A rms, 50-60 Hz	AC Input Power
Patient Cable	14 ft (4.3 m)	
Power Cable	10 ft (3 m)	
Optional internal battery	30 minute capacity	Nickel Metal Hydride
Optional noninvasive integrated blood pressure	Automatic with emergency deflate key Automatic over pressure protection	
External Input Fuse	2.0 Amp, Slo Blow, 250 V	
Environmental Specifications	Storage Temperature and Humidity Range: 0° C to 50° C, 0% to 95% RH Operating Temperature and Humidity Range: 10° C to 40° C, 10% to 95% RH	

11 MAINTENANCE

The BioZ.com® is a self-calibrating device and as such no internal adjustment of electrical components is required. To check the internal calibration, the User may attach the BioZ.sim™ (BZ-4525 or BZ-4575) patient simulator to verify the correct parameter specifications. See Model BZ-4525 or BZ-4575 Operational Instructions.

It is not possible for any internal testing to be performed on the BioZ.com®. The BioZ.com® does not have onboard diagnostic software.

11.1 Cleaning

It is recommended that the device and patient cable be periodically disinfected. This may be accomplished by wiping with a soft cloth dampened with a standard hospital disinfectant.

Note: Take appropriate precautions to ensure that no liquid or aerosol enters the internal portion of the BioZ.com®.

11.2 Patient Cable

The Patient Cable should be checked to ensure continuity of each connector every six (6) months or when there is doubt about the validity of the hemodynamic values.

No other periodic maintenance or inspection is required.

12 Z Care® Standard Warranty

CardioDynamics International Corporation ("CDIC") warrants that the BioZ® or BioZ.com® System ("System") and the System Software ("Software") shall be free from errors / defects in materials, workmanship, and programming that cause the System not to function in accordance with the accompanying written specifications provided with the System at the time of installation. *CDIC will provide this Warranty on each System for a period of sixty (60) months from the original CDIC invoice date.* This Warranty shall include all options and accessories purchased with the System except the external patient cable(s) and (if applicable) the external inflatable blood pressure cuff(s) and hose(s), which shall be covered under warranty for ninety (90) days from the original CDIC invoice date.

CDIC's and/or its Distributors' liability and obligation, and the End User's sole remedy shall be, at CDIC's option, to either repair or replace software and/or System or any part thereof. It is the responsibility of the End User to notify CDIC or CDIC's Distributor (if CDIC requests the End User to notify its Distributor) by telephone or in writing of any problem experienced by the End User within the sixty (60) month Warranty Period and no later than thirty (30) days after the expiration of the warranty period.

This Warranty does NOT apply to dual sensors, transducers, fuses, ink cartridges or other consumable or disposable items that are used in conjunction with the System.

Warranty Coverage:

- Customer / Technical Support is available Monday through Friday, 6 a.m. to 5 p.m. Pacific Time, at 800-778-4825 or 858-535-0202, option 3.
- CDIC will provide a loaner unit (equivalent or similar to purchased unit) within two (2) business days (U.S. Customers only) after it has been determined that the purchased unit needs repair. This determination needs to be made before 3:00 p.m. Pacific Time in order for the two (2) day loaner provision, and is dependent upon delivery services available to End User's location.
- CDIC will repair or replace any components of the System that cause the System to not function in accordance with the written materials provided with the System at time of sale.
- CDIC will provide free shipping and freight charges for original and loaner unit exchanges (UPS Ground or equivalent).
- CDIC will provide subsequent operational software upgrade disks and installation instructions at no charge to the customer.

Warranty Coverage is void if:

- The System and/or Software has been maintained, repaired, modified or altered by any person other than an authorized CDIC representative or without prior approval from and authorized CDIC representative.
- The System and/or Software has not been properly operated or maintained in accordance with CDIC's then applicable written operating and maintenance manuals.
- The configuration of the System and/or Software has been altered by, but not limited to, the addition of any other computer software to the System.
- The failure of the System and/or Software has resulted from accident, abuse, or misapplication.

- **Note:** There are no user-serviceable components in the BioZ® or BioZ.com®. All units must be returned to CDIC for repair or replacement during the warranty period.

CDIC does not warrant (either expressed or implied) the correctness or validity of any output information or data provided by the System, including, but not limited to, any information relating to any medical diagnosis/treatment or to the health and safety needs of patients. CDIC does not warrant that any output of the System will meet the standards or requirements of the End User's medical practice. End User expressly acknowledges that End User is solely responsible for verifying that any results produced by the System are free from error and suitable for the applications for which they are to be used.

CDIC and its authorized Distributors shall not be liable for any special, incidental, indirect or consequential damages arising out of the use of or inability to use the System.

Under no circumstances shall CDIC's and its Distributors' liability under this Limited Warranty exceed the purchase price of the System and/or Software paid by the End User.

13 SOFTWARE LICENSE AGREEMENT

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14 Appendix A. GLOSSARY OF TERMS

ACCELERATION INDEX (ACI) [100^{-1} sec^{-2}]: An index of the peak acceleration of aortic blood flow. The peak acceleration takes place approximately 15-30 msec after the opening of the aortic valve. ACI is a measure of the true inotropic state of the heart and is fairly independent of AFTERLOAD. The normal ranges for supine, resting adults are 70 – 150 x 100^{-1} sec^{-2} for males and 90 – 170 x 100^{-1} sec^{-2} for females.

$$ACI = 100 * (d^2Z/dt^2)/Z_o$$

ACI: See ACCELERATION INDEX.

AFTERLOAD: Represents the forces that the ventricle must overcome to deliver blood into the systemic vasculature during contraction. The primary component of afterload is vasoactivity, represented by Systemic Vascular Resistance (SVR). The secondary component of AFTERLOAD is blood viscosity. AFTERLOAD is a systolic phenomenon.

BASE IMPEDANCE (Z_0) [Ohm]: The mean electrical impedance of the thoracic cavity. Also known as THORACIC FLUID INDEX (TFI).

BODY SURFACE AREA (BSA) [m^2]: BSA is estimated by the DuBois and DuBois formula to be:

$$BSA = W^{0.425} \times H^{0.725} \times 0.007184$$

where H is the patient's height in cm, and W is their weight in kg.

BSA: See BODY SURFACE AREA.

CARDIAC INDEX (CI) [l min^{-1} m^{-2}]: The value of CARDIAC OUTPUT (CO) indexed by the BODY SURFACE AREA (BSA). The normal range for supine, resting adults is 2.5-4.7 l min^{-1} m^{-2}; mean value 3.6 l min^{-1} m^{-2}

$$CI = CO / BSA$$

CARDIAC OUTPUT (CO) [l/min]: The total volume of blood pumped by the heart in one minute. The normal range for adults is 4.5-8.5 liters per minute.

$$CO = SV * HR$$

CENTRAL VENOUS PRESSURE (CVP) [mmHg]: The pressure at the output of the systemic vasculature (filling pressure of the right heart). Normal mean value is 6 mmHg.

CI: See CARDIAC INDEX.

CO: See CARDIAC OUTPUT.

CONTRACTILITY: The rate of shortening of the myocardial muscle fibers in time. Contractility is a systolic phenomenon.

CVP: See CENTRAL VENOUS PRESSURE.

DIASTOLIC BLOOD PRESSURE (DBP) [mmHg]: The minimum arterial pressure (at the end of diastole).

DELTA Z (IMPEDANCE) WAVEFORM (deltaZ): The change in the thoracic base impedance due to the cardiac cycle.

dZ/dt [Ohms/sec]: The first derivative of the deltaZ waveform with respect to time. dZ/dt_{max} corresponds to the peak blood velocity in the aorta during systole.

d^2Z/dt^2 [Ohms/sec^2]: The second derivative of the deltaZ waveform with respect to time. d^2Z/dt^2_{max} corresponds to the peak blood acceleration in the aorta during systole.

ELECTRICAL BIOIMPEDANCE (EB): A noninvasive technique for converting the measurement of electrical conductivity of a body segment into the blood flow through the segment and the content of fluids within the segment.

HEART RATE (HR) [beats min^{-1}]: The number of beats performed by the heart in one minute.

HEMODYNAMIC MODULATORS: The parameters that affect (modulate) blood flow and blood pressure.

HR: See HEART RATE.

HYPERDYNAMIC STATE: The supernormal or abnormally high value for a specific condition.

HYPERTENSION: A state where the mean arterial pressure exceeds 100 mmHg (supine, resting adults).

HYPODYNAMIC STATE: The infranormal or abnormally low value for a specific condition.

HYPOTENSION: A state where the mean arterial pressure is lower than 84 mmHg (supine, resting adults).

INOTROPY: Myocardial contractility or, the force of contraction. Normoinotropy is an adequate (normal) inotropic state; hypoinotropy is an inadequate (infranormal) inotropic state [corrected therapeutically through the use of positive inotropic therapy/support]; hyperinotropy is an excessive (supranormal) level of inotropic state [corrected therapeutically through the use of negative inotropic therapy].

LCW: See LEFT CARDIAC WORK.

LCWI: See LEFT CARDIAC WORK INDEX.

LEFT CARDIAC WORK (LCW) [kg m]: The measure of work which the left ventricle must expend to pump blood; it is a product of the ventricular pressure contribution (MAP - PAOP), CO, and a constant (unit conversion factor). LCW is proportional to the myocardial oxygen consumption. The normal range for supine, resting adults is, 5.4 – 10.0 kg m.

$$LCW = (MAP - PAOP) * CO * 0.0144$$

LEFT CARDIAC WORK INDEX (LCWI) [kg m m^{-2}]: A value of LEFT CARDIAC WORK (LCW) indexed by the BODY SURFACE AREA (BSA). LCWI is a product of the ventricular pressure contribution (MAP - PAOP), CI, and a constant. The normal range for supine, resting adults, 3.0 - 5.5 kg m m^{-2}.

$$LCWI = (MAP - PAOP) *CI * 0.0144$$

LEFT STROKE WORK INDEX (LSWI) [g m m^{-2}]: The measure of work which the left ventricle must expend to pump blood per heart beat; it is a product of the ventricular pressure contribution (MAP - PAOP), SI, and a constant. The normal range for LSWI, based on the ideal hemodynamic state where, SI = 50 ml/m^2, MAP = 92 mmHg, PAOP = 10 mmHg is: 47.2 – 70.8 g m m^{-2}.

LEFT VENTRICULAR EJECTION TIME (LVET) [msec]: The time between the opening and closing of the aortic valve.

LSWI: See LEFT STROKE WORK INDEX.

MEAN ARTERIAL PRESSURE (MAP) [mmHg]: A measure of the average arterial perfusion pressure, which determines blood flow to the tissues.

NORMODYNAMIC STATE: When the CARDIAC INDEX (CI) is within its respective normal range (normodynamic = adequate global blood flow level for a specific condition).

NORMOTENSION: A state where mean arterial pressure (MAP) is within a normal range. The normal MAP range for supine, resting adults is 84 - 100 mmHg.

PAOP: See PULMONARY ARTERY OCCLUDED PRESSURE.

PEP: See PRE-EJECTION PERIOD.

PRE-EJECTION PERIOD (PEP) [msec]: The period of isovolumetric ventricular contraction.

PULMONARY ARTERY OCCLUDED PRESSURE (PAOP) [mmHg]: The filling pressure of the left heart. Normal, mean value is 10 mmHg.

SI: See STROKE INDEX.

SSRI: See STROKE SYSTEMIC VASCULAR RESISTANCE INDEX. Same as SSVRI.

SSVRI: See STROKE SYSTEMIC VASCULAR RESISTANCE INDEX.

STROKE INDEX (SI) [ml/m^2]: STROKE VOLUME indexed by BODY SURFACE AREA.

$$SI = SV / BSA$$

STROKE SYSTEMIC VASCULAR RESISTANCE INDEX (SSVRI or SSRI) [dyne cm^{-5} m^2]: A measure of afterload. It is calculated by substituting SI for CI in the SVRI equation. [((MAP - CVP)/SI) x 80]. The normal range for SSRI, based on the ideal hemodynamic state where, SI = 50 ml/m^2, MAP = 92 mmHG, CVP = 6 mmHg is: 110 – 165.

STROKE VOLUME (SV) [ml]: The volume of blood delivered by the heart into the vasculature in one beat.

SV: See STROKE VOLUME.

SVR: See SYSTEMIC VASCULAR RESISTANCE.

SVRI: See SYSTEMIC VASCULAR RESISTANCE INDEX.

SYSTEMIC VASCULAR RESISTANCE (SVR) [dyne sec cm^{-5}]: The vascular resistance of the systemic vasculature as seen by the left ventricle (afterload). Normal range for a supine, resting adult is: 770 – 1500 dyne sec cm^{-5}.

$$SVR = 80 * (MAP - CVP) / CO$$

SYSTEMIC VASCULAR RESISTANCE INDEX (SVRI) [dyne sec cm^{-5} m^2]: SVRI represents the primary component of afterload. The normal range of SVRI for a supine, resting adult is: 1337 to 2483 dyne sec cm^{-5} m^2.

$$SVRI = 80 * (MAP - CVP) / CI$$

SYSTOLIC BLOOD PRESSURE (SBP) [mmHg]: The highest level of arterial blood pressure reached with each heart beat.

SYSTOLIC TIME RATIO (STR): Calculated by the systolic time intervals (STI) of PRE-EJECTION PERIOD (PEP) and LEFT VENTRICULAR EJECTION TIME (LVET).

$$STR = PEP / LVET$$

TEB: See THORACIC ELECTRICAL BIOIMPEDANCE.

TFC: See THORACIC FLUID CONTENT.

TFI: See THORACIC FLUID INDEX.

THORACIC ELECTRICAL BIOIMPEDANCE (TEB): The special utilization of Electrical Bioimpedance for thoracic measurements, producing a measurement of global blood flow (CO/CI, SV/SI), Thoracic Fluid Content (TFC), base impedance and the parameters of left ventricular performance – VI and ACI, (Velocity Index, Acceleration Index).

THORACIC FLUID CONTENT (TFC) [$kOhm^{-1}$]: The total conductivity of the thorax, representing parallel conductivity contributions of three compartments: intravascular, intra-alveolar and interstitial. The normal ranges are 30 – 50 for males and 21 – 37 for females. Excessive TFC value indicates an excess in thoracic fluids, however, it does not specify if the fluids are in the intravascular, intra-alveolar or interstitial compartment(s).

$$TFC = 1000 / Z_o$$

THORACIC FLUID INDEX (TFI) [Ohm]: See BASE IMPEDANCE.

VASOACTIVITY: Vasoactivity is a change in vessel diameter, controlling vascular resistance of the vessel's blood flow rate.

VELOCITY INDEX (VI) [1000^{-1} sec^{-1}]: Is a measurement of normalized peak aortic flow. VI is a preload/volume-dependent measure of contractility. The normal range for supine, resting adults is: 33 – 65 x 1000^{-1} sec^{-1}.

$$VI = 1000 * (dZ/dt) / Z_o$$

VI: See VELOCITY INDEX.

WEDGE PRESSURE: A term that is often used simultaneously, although incorrectly, for Pulmonary Artery Occluded Pressure (PAOP). This term dates back to times before the introduction of the occlusive balloon. At that time, the catheter was actually 'wedged' into a small pulmonary artery in order to measure the filling pressure of the left heart.

Z_0: See BASE IMPEDANCE.

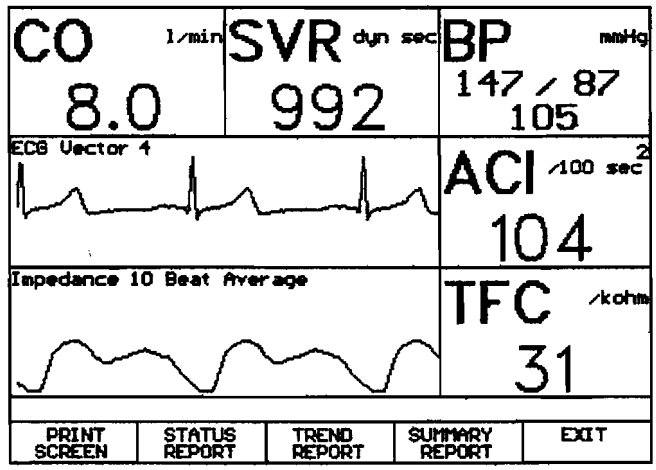
15 Appendix B. PRINT SCREEN REPORT

CDIC MEDICAL CENTER
1234 MAIN STREET, SUITE 234, SAN DIEGO, CA 92121

Print Screen Report

Name:	JOHN DOE	**Age:**	76	**Height:**	6 ft 4 in
ID:	125785612	**Sex:**	Male	**Weight:**	235 lb
				BSA:	2.37 m^2

Page 1 of 1



Clinical Note:_____

_____

Data Collection:
Report Generated: 03/22/00 at 15:33 **Signature:**_____

CardioDynamics

16 Appendix C. HEMODYNAMIC SUMMARY REPORT

CDIC MEDICAL CENTER
1234 MAIN STREET, SUITE 234, SAN DIEGO, CA 92121

Hemodynamic Summary Report

Name:	JOHN DOE	**Age:**	76	**Height:**	6 ft 4 in
ID:	125785612	**Sex:**	Male	**Weight:**	235 lb
				BSA:	2.37 m²

Total Monitoring Time 00:14 **Page 1 of 1**

Time	BP(MAP)	HR	CO	SVR		ACI	TFC	Event
15:21:08	147/87(105)	70	8.0	992		106	31	
15:22:25	147/87(105)	70	8.0	986		105	31	
15:23:16	147/87(105)	70	8.0	989		104	31	
15:24:07	147/87(105)	70	8.0	985		104	31	
15:25:25	147/87(105)	70	8.1	982		103	31	
15:26:16	147/87(105)	70	8.0	991		104	31	
15:27:07	147/87(105)	70	8.0	990		104	31	
15:28:24	147/87(105)	70	8.0	995		103	31	
15:29:15	147/87(105)	70	8.1	983		104	31	
15:30:06	147/87(105)	70	8.0	989		104	31	
15:31:22	147/87(105)	70	7.9	1004		104	31	
15:32:13	147/87(105)	70	8.0	989		104	31	
15:33:05	147/87(105)	70	8.0	992		104	31	
15:34:22	147/87(105)	70	8.0	986		103	31	
15:35:13	147/87(105)	70	8.0	985		105	31	
Average	**147/87(105)**	**70**	**8.0**	**989**		**104**	**31**	
Normal Ranges	84-100 mmHg	58-86 bpm	5.9-11.2 l/min	742-1378 dyn sec		90-170 /100 sec	21-37 /kmhm	

Clinical Note:_____

Data Collection: 03/22/00
Report Generated: 03/22/00 at 15:36 **Signature:**_____

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17 Appendix D. HEMODYNAMIC TREND REPORT

CDIC MEDICAL CENTER
1234 MAIN STREET, SUITE 234, SAN DIEGO, CA 92121

Hemodynamic Trend Report

Name:	JOHN DOE	**Age:**	76	**Height:**	6 ft 4 in
ID:	125785612	**Sex:**	Male	**Weight:**	235 lb
				BSA:	2.37 m²

Page 1 of 1

Trend Parameter	Parameter Values	% Time WNL
CO (16.4 / 11.2 / 5.9 / 0.7)	Max: 8.1 Avg: 8.0 Min: 7.9	100 %
SVR (2014 / 1378 / 742 / 106)	Max: 1100 Avg: 991 Min: 978	100 %
MAP (116 / 100 / 84 / 68)	Max: 116 Avg: 105 Min: 105	0 %
ACI (230 / 150 / 70)	Max: 111 Avg: 104 Min: 102	100 %
TFC (70 / 50 / 30 / 10)	Max: 31 Avg: 31 Min: 31	100 %

12:09 12:34 13:00 13:25 13:51 *Time*
Event

Event	Time	Description	Event	Time	Description

Data Collection: 03/22/00 From 12:09-13:50
Report Generated: 03/22/00 at 13:51 **Signature:**_____

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18 Appendix E. HEMODYNAMIC STATUS REPORT

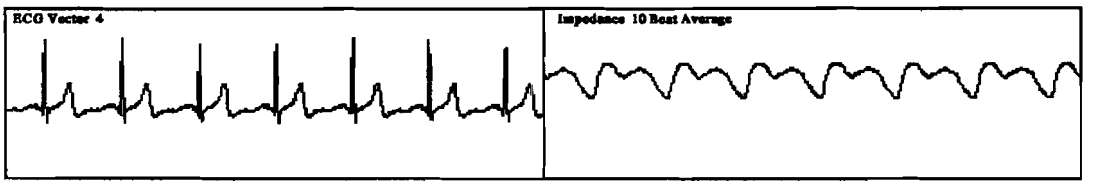
CDIC MEDICAL CENTER
1234 MAIN STREET, SUITE 234, SAN DIEGO, CA 92121

Hemodynamic Status Report

Name:	JOHN DOE	**Age:**	76	**Height:**	6 ft 4 in
ID:	125785612	**Sex:**	Male	**Weight:**	235 lb
				BSA:	2.37 m^2

10 Beat Average **Page 1 of 1**

Parameter	Description	Value	Low	Normal	High
HR	Heart Rate	70	58	86	
SBP	Systolic Blood Pressure	147	100	140	
DBP	Diastolic Blood Pressure	87	60	90	
MAP	Mean Arterial Pressure	105	84	100	
CI	Cardiac Index	3.4	2.5	4.7	
CO	Cardiac Output	8.0	5.9	11.2	
SI	Stroke Index	49	35	65	
SV	Stroke Volume	115	83	154	
SVRI	Systemic Vascular Res. Index	2325	1337	2483	
SVR	Systemic Vascular Resistance	985	742	1378	
ACI	Acceleration Index	104	70	150	
VI	Velocity Index	47	33	65	
TFC	Thoracic Fluid Content	31	30	50	
LCWI	Left Cardiac Work Index	4.7	3.0	5.5	
LCW	Left Cardiac Work	11.0	5.4	10.0	
STR	Systolic Time Ratio	0.43	0.30	0.50	
PEP	Pre-Ejection Period	119			
LVET	Left Ventricular Ejection Time	270			



Clinical Note:_____

Data Collection: 03/22/00 at 12:44
Report Generated: 03/22/00 at 12:45 **Signature:**_____

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19 INDEX

A

Acceleration Index (ACI) 105
Afterload 105
Age 45
Alarm ON/OFF 11
Alarm Reset 11
Alarms 63

B

Base Impedance (Z_0) 105
Battery 12
BioZ.com® Cuff 46
Body Surface Area (BSA) 105
Built-in Noninvasive Blood Pressure Monitor 6

C

Cardiac Index (CI) 105
Cardiac Output (CO) 105
Central Venous Pressure (CVP) 105
Charge 12
Clear 10
Configure Screens 27, 78
Configure Status Report 77
Contractility 105
Contraindications 4

D

d^2Z/dt^2 106
Delta Z (Impedance) Waveform 105
Diagnostic Screen
  Configuring 80
dZ/dt 105

E

ECG Vectors 52
Enter 10
Event 9
Exiting a Monitoring Session 35

F

Facility Name 75

G

Gender 43
General System Overview 7
GLOSSARY 105

H

Hardkeys 8
  Alarm ON/OFF 11
  Clear 10
  Enter 10
  Event 9
  Previous Screen 9
Heart Rate (HR) 106
Height 44

I

ICG Sensor Application 37
ICG Sensors 37
Indications 4
Internal Battery Power 6

L

LED Indicators 12
Left Ventricular Ejection Time (LVET) 106
Low Battery 94

M

Mains AC 12
Maintenance 99
Manual Deflate 12
Mean Arterial Presure (MAP) 107
Menu 8
Monitor Screen
  Configuring 79
Monitoring Screen 52

N

Next Screen 9
NIBP Port 14
Nominal Specifications 97
Normal Ranges 66

O

Optional Features 6

P

Patient Data Entry Fields 41
Patient Diagnostic Screen 54
Patient ID 41
Patient Monitoring 25, 37
Patient Monitoring Screens 51
Patient Name 42
Patient Preparation 37
Patient Therapeutic Screen 55
Patient Trend Screen 57
Power Source Status 12
Precautions 3
Pre-Ejection Period (PEP) 107
Previous Screen 9
Print 11
Printing Information 89
Pulmonary Artery Occluded Pressure (PAOP) 107

Q

Quick-Start Instructions 17

R

Reports
Hemodynamic Status Report 90
Hemodynamic Summary Report 89
Hemodynamic Trend Report 90
Print Screen Report 89
Reviewing Patient Records 34, 35, 85

S

Serial Input 15
Serial Output 15
Signal Acquisition Error 93
Signal Strength Status 13
Skin Preparation 37
Softkeys 8
SOFTWARE LICENSE AGREEMENT 103
Standard Features 5
Stop Monitoring 10
Stroke Index (SI) 107
Stroke Volume (SV) 107
System Defaults 70
System Set-up 62
Systemic Vascular Resistance (SVR) 107
Systemic Vascular Resistance Index (SVRI) 107
Systolic Time Ratio (STR) 107

T

TEB 1
Theoretical Concepts 1
Thoracic Fluid Content (TFC) 108
Thoracic Fluid Index (TFI) 108
Troubleshooting 93

U

Update Patient Information 84
User Interface (Symbol Key) 8

V

Velocity Index (VI) 108

W

WARNINGS AND PRECAUTIONS ..... 3. *See*
General Warnings 3
Warranty 101
Waveform Recording Options 76
Waveform Screen
Configuring 82
Weight 44
Welcome Screen 61

CardioDynamics

DECLARATION OF CONFORMITY
93/42/EEC

Manufacturer:	CardioDynamics International Corporation
Address:	6175 Nancy Ridge Drive San Diego, California 92121 USA
Product Designation:	Hemodynamic Monitor
Product Name:	BioZ.com
Model Numbers:	BZ-4110*-***, BZ-4100*-***, BZ-4000*-***, BZ-4010*-***
Authorized Representative:	Donawa Italia Srl Via Fonte Di Fauno, 22 Rome 00153 Italy

We herewith declare that the above products meet the provisions of EC Directive 93/42/EEC which apply to them, as stated in Annex I and Annex II of this directive.

Certification under Annex II

Certificate Number:	HD 9811719 01
Issued by:	TÜV Rheinland Product Safety GmbH

Place, date:	SAN DIEGO CA 6/12/2002
Signature:	
Name:	MICHAEL R. PERRY
Title:	CHIEF EXECUTING OFFICER

CE
0197